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THESIS

IMPLEMENTING THE NATIONAL FRAMEWORK FOR A BIOTHREAT FIELD RESPONSE MISSION CAPABILITY

by

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September 2013

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Since the 2001 anthrax attacks, communities have been responding to a sample surge of suspicious mailings. Each event has the potential to be an act of bioterrorism involving a deadly pathogen and, thus, requires a timely response in order to evaluate the risk to public safety. Stakeholders from federal and state governments and industry have recognized the need to develop a mission capability for responding to these suspicious events. The framework for a biothreat field response mission capability advocates the use of innovative detection technology in support of a risk assessment concept of operation. Implementing the framework will require federal and state collaboration and will establish local certification training standards, field-based proficiency and competency assessment exercises, and state response plans that reflect national guidance. This research describes the critical elements of a bioresponse framework, the current status of framework adoption at the state level, and recommendations for a three-phased implementation model.

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IMPLEMENTING THE NATIONAL FRAMEWORK FOR A BIOTHREAT FIELD RESPONSE MISSION CAPABILITY

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ABSTRACT

Since the 2001 anthrax attacks, communities have been responding to a sample surge of suspicious mailings. Each event has the potential to be an act of bioterrorism involving a deadly pathogen and, thus, requires a timely response in order to evaluate the risk to public safety. Stakeholders from federal and state governments and industry have recognized the need to develop a mission capability for responding to these suspicious events. The framework for a biothreat field response mission capability advocates the use of innovative detection technology in support of a risk assessment concept of operation. Implementing the framework will require federal and state collaboration and will establish local certification training standards, field-based proficiency and competency assessment exercises, and state response plans that reflect national guidance. This research describes the critical elements of a bioresponse framework, the current status of framework adoption at the state level, and recommendations for a three-phased implementation model.

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LIST OF ACRONYMS AND ABBREVIATIONS

ALS	Analytical Lab System
APHL	Association of Public Health Laboratories
ASTM	American Society for Testing and Materials
BT	Biological Terrorism
CBRNE	Chemical, Biological, Radiological, Nuclear, Explosive
CDC	Centers for Disease Control and Prevention
ConOp	Concept of Operation
CRP	Critical Reagents Program
CST	Civil Support Team
DHS	Department of Homeland Security
DTRA	Defense Threat Reduction Agency
EMS	Emergency Medical Services
FBI	Federal Bureau of Investigation
GAO	Government Accountability Office
HAZMAT	Hazardous Materials
LRN	Laboratory Response Network
NGB	National Guard Bureau
NIST	National Institute of Standards and Technology
OVS	Operation Vigilant Sample
PCR	Polymerase Chain Reaction
PHAA	Public Health Actionable Assay
PSAA	Public Safety Actionable Assay
PT	Proficiency Test
QA	Quality Assurance
S&T	Science and Technology
USPIS	Untied States Postal Inspection Service
WMD	Weapons of Mass Destruction

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I. INTRODUCTION/RATIONALE

A. INTRODUCTION

Emergency responders[1] in the United States respond to suspicious substances and packages as a matter of routine. Since the 2001 anthrax attacks, law enforcement agencies in the United States have responded to over 30,000 suspect events.[2] Each event required a law enforcement investigation, sample collection by a qualified hazardous materials (HAZMAT)[3] team, and laboratory analysis to clear the suspected material of being hazardous. Each event was initiated through a public complaint, resulting in varying levels of social and economic disruption, and caused uncertainty in the minds of those directly related with the on-scene response. A sample surge phenomena has become the legacy of the post-9/11 era. Nearly all of the 30,000-plus suspicious substance events since then were found not to be acts of terrorism, but nonetheless they did create significant disruption, public fear and economic damage.[4] Rarely do these incidents involve real hazards, and sometimes they turn out to be nothing more than a practical joke. The Federal Bureau of Investigation (FBI) treats these incidents as real events and will prosecute the senders if they can be arrested.[5] Regardless of the low probability of an actual biological threat incident, emergency responders and law enforcement must react

[1] An "emergency responder" includes state, local, and tribal emergency public safety, law enforcement, emergency response, emergency medical (including hospital emergency facilities), and related personnel, agencies, and authorities. See Section 2 (6), *Homeland Security Act of 2002*, Pub. L. 107-296, 116 Stat. 2135 (2002). ASTM International, *E2770-10: Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent* (West Conshohocken, PA: ASTM International, 2010), 3, retrieved May 10, 2012, from http://www.astm.org/DHS/E2770.pdf.

[2] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability*, (Washington, DC: Department of Homeland Security, 2011), 3.

[3] A "HAZMAT responder" is a trained and certified individual who is a member of a hazardous material response team or qualified to respond to incidents involving toxic industrial chemicals, chemical warfare agents and other weapons of mass destruction, or both. A HAZMAT response specialist will have additional training to respond to specific weapons of mass destruction. ASTM International, *E2770-10: Standard Guide for Operational Guidelines*, 3.

[4] Fox News, "White Powder Case Costs Millions in First Response," *Fox News*, May 17, 2012, retrieved August 13, 2013, from http://www.foxnews.com/us/2012/05/17/white-powder-case-costs-millions-in-first-response/.

[5] Federal Bureau of Investigation, "Reward Offered in White Powder Letters Case," Federal Bureau of Investigation News Blog, May 16, 2012, http://www.fbi.gov/news/news_blog/white-powder-letters_051612.

to each event with the potential for the suspect material or package to be a weapon of mass destruction (WMD). The potential for catastrophe requires that a timely deployment of a biothreat response mission capability to determine the true threat and hazard of each event.

Following the anthrax attacks in Florida, Washington, D.C., and New York the sample surge phenomena increased so rapidly that emergency responders and the laboratories that could handle biological samples for the federal government were quickly overwhelmed with the sheer volume of incidents. At that time, there were no validated methods or a coordinated concept of operations (ConOp) to aid in sample collection.[6] Competing concerns over public health and law enforcement objectives complicated emergency responder actions even more. Often, environmental samples were consumed on-site in an attempt to make field identification with no material remaining for confirmatory analysis at a certified laboratory. Samples that did make it to a public health laboratory were typically described as "unusual and unusable."[7] In March 2005, the United States Government Accountability Office (GAO) issued a report that was critical of the 2001 anthrax response,[8] GAO-05-251, *Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results*. In the GAO's view, "the lack of validation of agencies' activities, coupled with limitations associated with their targeted sampling strategy, means that negative results may not be reliable."[9] The GAO went on to recommend that the Secretary of Homeland Security take on the task of ensuring that sample collection and pathogen detection methods are validated and to coordinate the different agencies' efforts in environmental testing.[10] Although the focus of GAO-05-251 was not specifically on the on-site biological

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[6] Laurie Locascio, "Department of Homeland Security and Committee E54 Lead the Way," last modified August 2006, ASTM International, retrieved June 18, 2013, from http://www.astm.org/SNEWS/AUGUST_2006/locascio_aug06.html.

[7] Ibid.

[8] United States Government Accountability Office [GAO], *Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results* (GAO-05-251), (Washington, DC: United States Government Accountability Office, 2005), retrieved July 21, 2013, http://www.gao.gov/new.items/d05251.pdf.

[9] Ibid., abstract.

[10] Ibid.

assessment and threat evaluation process conducted by emergency responders during the initial phase of recognition and response, the findings were relevant to these shareholder communities.

The concerns in detection capability were identified again in 2008 in GAO-08-180, First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas is Significantly Limited. GAO-08-180 differed from GAO-05-251 in that it was specific to emergency responders. That report stated, "Handheld detection devices for biological agents are not reliable or effective."[11] It also recognized that DHS has the primary mission to develop, independently test, and certify emergency responder detection equipment.[12] The reports became a call to action; when the Center for Disease Control and Prevention (CDC), United States Postal Service (USPS), and the Department of Homeland Security (DHS) read the draft report, they all agreed that methods for detecting anthrax were not validated and that a systematic validation effort was needed.[13] Over concerns from Congress regarding the suitability of handheld assays for field assessment, stakeholders from federal and state agencies participated in an interagency working group to define a framework in order to improve the reliability and accuracy of on-site testing results.[14]

In May 2011, the White House released *A National Strategy for CBRNE Standards*.[15] The document described the strategy for the adoption of national standards:

> To confidently prepare for and respond to CBRNE incidents, Federal, State, Local and tribal governments must be guided and supported by

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[11] United States Government Accountability Office [GAO], *First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas is Significantly Limited* (GAO-08-180) (Washington, DC: United States Government Accountability Office, 2008), retrieved July 21, 2013, from http://www.gao.gov/new.items/d08180.pdf.

[12] Ibid., 26.

[13] Center for Infectious Disease Research and Policy, "GAO Questions Anthrax Detection Methods," last modified April 18, 2005, Center for Infectious Disease Research and Policy, University of Minnesota, retrieved June 13, 2013, from http://www.cidrap.umn.edu/cidrap/content/bt/anthrax/news/april1805anthrax.html.

[14] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability*, 3.

[15] White House, *National Security Strategy* (Washington, DC: White House, 2010), 18, White House, retrieved May 10, 2012, from http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf.

> standards. Standards for CBRNE range from standards for equipment performance, interoperability, operating procedures, and training certification of responders, to the test and evaluation of CBRNE equipment.[16]

Innovation and technology are changing how communities respond to suspicious powder events. Without integrated tools for assessing hazards, traditional response models are becoming outdated. As emergency responders have adapted to the increasing prevalence of the next generation of detection systems, such as real-time polymerase chain reaction (PCR), some communities are transforming their capabilities into mobile extensions of the traditional brick and mortar laboratory. Innovation has made it possible for emergency responders to produce on-scene assessments that were not possible pre-9/11. If the national response frameworks does not take into account the prevalence of new technologies, it risks becoming outdated. Some agencies are reluctant to accept the utility of detectors because of limitations surrounding the quality of their results, which has led to challenges in developing a national framework that integrates innovative technology. For example, it is the position of the Association of Public Health Laboratories (APHL) to oppose the use of field-based detection because of issues surrounding the lack of standardization and validated performance.[17]

In 2011, a national framework for biothreat response was published; it addresses the challenges of technology integration for detection technology and the need to standardize. The *Framework for a Biothreat and Response Mission Capability*[18] is supported by five critical mission elements that enable coordination amongst responding agencies and confidence in assay results. The five elements are:

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[16] Ibid.

[17] Association of Public Health Laboratories, *Standardized Validation of Screening Kits and Devices for Use in the Field to Identify Hazardous Biological and Chemical Agents*, November 2006, Association of Public Health Laboratories, retrieved December 4, 2012, from http://www.aphl.org/policy/Documents/Field_Devices.pdf.

[18] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability*.

1. A concept of operations (ConOps) to support use of fielded assays and coordination of response among the key stakeholders in the jurisdiction;
2. Training and certification of end-users;
3. Proficiency testing in the hands of the end-user in the field;
4. Sample collection and handling standards; and
5. Assays that have been properly tested by a qualified third party and certified to meet or exceed appropriately recognized national voluntary consensus standards for performance.[19]

The publication of *ASTM E2770-10* met the first critical element, which pertains to the biothreat response ConOp.[20] The ConOp defines the hazard assessment and threat evaluation process as HAZMAT and law enforcement responsibilities, respectively. The initial response is the point where technology can have the greatest impact on changing the way a suspect event is resolved. The ConOp defines the role for technology to facilitate the hazard assessment process.

The second and third elements, certified training and field delivered proficiency testing, have not been accomplished at the national level, but some work has been accomplished at the state level that demonstrates these elements are achievable. The fourth critical element, sample handling standards, was achieved through publication of *ASTM E2458-10*, which is a sample collection standard.[21] The standard is a two-part method. "Method A" is for the collection of bulk powder and any accompanying letters, and "Method B" is for the collection of remaining trace residual powder. *E2458-10* is a sample split method at point of sample.[22] Method A is for a state's public health laboratory, and method B is for on-site testing. *E2458-10* marks a significant change in the national response doctrine for suspected biological threats because the method recognizes the need for on-site testing. Lastly, progress has been made on the fifth element, validated assays, through the development of national consensus performance

[19] Ibid. 3.

[20] Ibid. 4.

[21] Ibid. 4.

[22] ASTM International, *E2458-10: Standard Practices for Bulk Sample Collection and Swab Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Surfaces* (West Conshohocken, PA: ASTM International, 2010), retrieved May 10, 2012, from http://www.astm.org/DHS/E2458.pdf.

standards that define the minimum performance requirements for assays that evaluate suspicious powders for *B. anthraces* and ricin toxin in the field.

The national framework goes on to define two field-based assays and one confirmatory assay. The first field-based assay is the "on-site biological assessment" or field safety screening.[23] It is conducted at point of sample before the sample is collected. Screening results are used to support the hazard assessment, which is then combined with a law enforcement threat evaluation in order to determine an incident's risk assessment. The risk assessment defines what actions should occur, or how the response should proceed, such as the need to collect and test a sample. Therefore, screening should accomplish two things: determination if the sample is safe to handle and base characterization of the sample. Currently, characterization screening is not an accepted part of the national framework, only safety screening. The need for characterization screening, which is a component of an "on-site biological assessment,"[24] will be addressed later in this thesis and recommendations on how to incorporate results into the framework ConOp will be made in the Conclusion Section.

The other field-based assay is the public safety actionable assay (PSAA), which is used to presumptively identify an unknown substance.[25] Method B, or on-site samples, are for PSAA. PSAAs support public safety actions such as shutting down a facility, determining proper decontamination procedures, and other contamination control procedures. These are considered ascending protective actions. Under some very specific circumstances, PSAA can be used in determining descending protective actions, such as downgrading personal protective equipment ensembles. Negative PSAAs cannot be used to rule out the presence of all biological threats. Therefore, method A, or off-site samples, must be tested for confirmation by the laboratory response network (LRN) laboratory via the third type of assay, Public Health Actionable Assay (PHAA). PHAA are considered definitive and results can be used to support medical response and public messaging.

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[23] Department of Homeland Security, *Framework for Biothreat Field Response Mission* Capability, 5.

[24] An "on-site biological assessment" is a measurement of properties inherent to biological materials performed in the field using rapid, field based procedures, and assays. ASTM International. *E2770-10: Standard Guide for Operational Guidelines*, 3.

[25] For the purpose of this paper "PSAA" maybe interchangeable with "presumptive analysis."

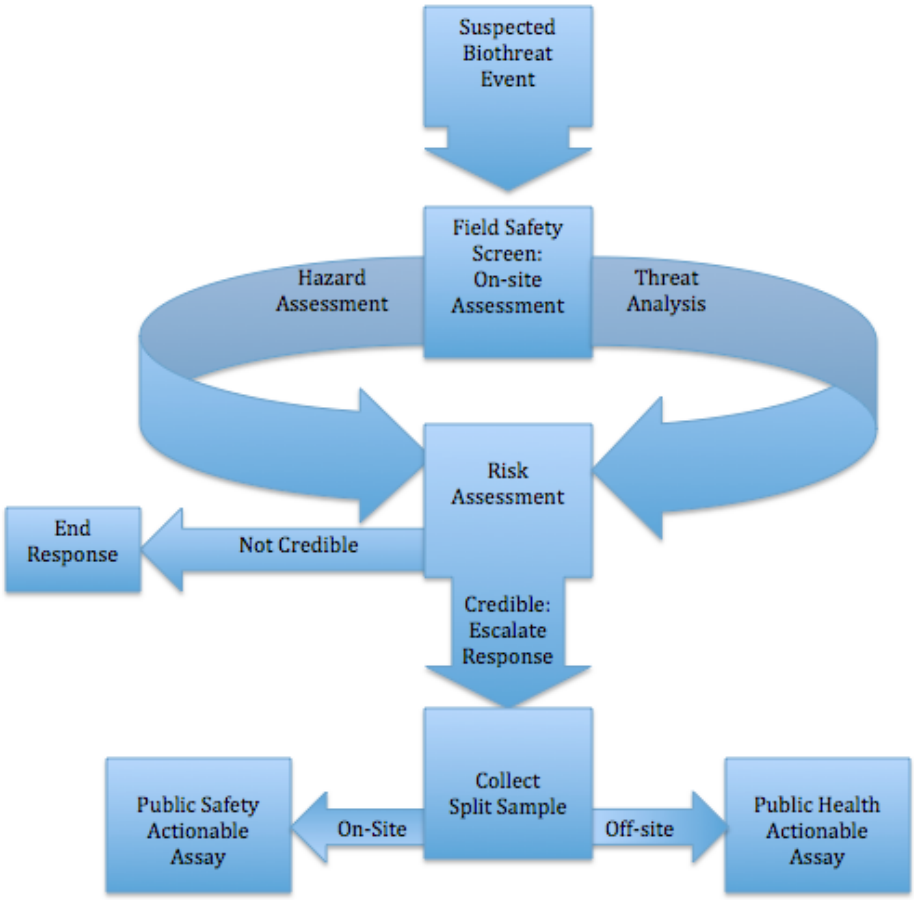

Figure 1. Bioresponse ConOp

B. PROBLEM STATEMENT

The bioresponse framework was developed in reaction to the sample surge phenomena post-9/11. At its very core, the framework is a triage process to quickly and accurately evaluate the level of risk of a suspected event in order to determine how to proceed during the initial hours of a response. Technology is the driving force behind change, and it is unknown how local emergency responders are incorporating the technology into the ConOp. It is unknown how the framework will support emergency responder use of the technology in terms of quality assurance (QA), training and competency and proficiency assessment.

The disruptive effects of integrating innovative technology can lead to evolutionary changes in response operations similar to what happened when the

emergency medical services (EMS) system was implemented in the late 1960s. In the EMS community, technology, methodologies, and credentialing transformed the ambulance from simple transport to an extension of the emergency room. Similarly, HAZMAT teams are also transforming, becoming the field response units for their state's public health laboratory.[26] Advances in portable detection, such as real-time PCR and lateral flow immunoassays, hold great potential to positively impact local preparedness levels.

The demand for detection technology is growing rapidly as the nation experiences yet another round of biothreat mailings.[27] It is unclear how many portable detectors are in use by emergency responders, but it is clear that equipment manufacturers are directly marketing to them.[28] Detection capability at this level requires a ConOp and a QA program in order to standardize results and increase reliability.[29] Without standards, communities will be left vulnerable to false positive and false negative results. Implementation of a standardized QA program will reduce the incidence of faulty results and increase preparedness. State governments and their public health laboratories do not have clear guidance on how to implement the national biothreat response framework. Due to "home-rule," the federal government cannot direct implementation; like the EMS example, framework implementation must occur at the state and community levels. [30] It

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[26] Jayne Morrow, Clay McGuyer, Bryon Marsh, David Ladd, "Building a National Biothreat Response Capability," *Defense Standardization Program Journal* (April/September 2012), 26.

[27] Paul Harris, "Bit-Part Actor Charged over Plot to Frame Husband for Ricin Letters," *The Guardian*, June 8, 2013, retrieved July 21, 2013, from http://www.guardian.co.uk/world/2013/jun/08/shannon-richardson-ricin-plot-husband.

[28] A. Bird, D. Kadavy, A. Vinas, L. Allen, N. Westfall, R. Carrion, K. Hoosien, M. Redon, C. Christensen, J. Gardner, R. Trauscht, R., Crisp, D. Stordal, and J. Nunneley, *Field Based Real-Time PCR Detection of Biothreat Pathogens Without Sample Extraction or Purification*, 2013, BioFire, retrieved June 24, 2013, from, http://www.biofiredx.com/pdfs/Posters/2011/Field%20Based%20PCR%20Detection%20Pathogens%20Without%20Sample%20Extraction%20or%20Purification-0111Pstr.pdf.

[29] Centers for Disease Control and Prevention [CDC] and National Guard, *The Role of the Civil Support Team in Support of the Laboratory Network* (Atlanta, GA: Centers for Disease Control and Prevention and National Guard Bureau, 2009), 12–13.

[30] Diane Lang, "Dillon's Rule…And the Birth of Home Rule," Reprinted from *The Municipal Reporter*, December, 1991, New Mexico Municipal League, retrieved August 13, 2013, from http://nmml.org/wp-content/uploads/Dillon's-Rule-The-Birth-of-Home-Rule.pdf.

is expected that significant variation from state to state in ConOp and QA will be observed if a national implementation model is not developed.

The bioresponse framework is defined by the five elements of the *Framework for a Biothreat and Response Mission Capability* and confirmed again in the *APHL Model Practice: Algorithm and Guidelines for Responding to an Incident Involving a Suspicious Non-Clinical Sample.*[31] The framework has matured throughout the interagency process that developed it and has been implemented in part at the federal, but not at the state level. The FBI and LRN utilize the ConOps to determine risk, but the other elements of the framework have not been implemented. Currently, the biothreat response community lacks a national training curricula and coordinated efforts to assess proficiency and competency. Additionally, there have been no comprehensive studies of what elements of the framework have been adopted at the state and local levels.

C. GOALS AND OBJECTIVES

The purpose of this research is to identify the barriers and best practices to implementation of a national biothreat response framework. The research will examine what actions state public health agencies are taking towards implementation, how emergency responders can incorporate technology, the lessons learned from the National Guard's Civil Support Team program, and if an implementation model can be developed.

D. RESEARCH QUESTIONS

The following are the research questions:

- *What is the current state of framework adoption at the state level?*
- *What is the national bioresponse framework?*
- *What is the framework implementation model?*

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[31] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability.* 3; Association of Public Health Laboratories, *Association of Public Health Laboratories Model Practice: Algorithm and Guidelines for Responding to an Incident Involving a Suspicious Non-Clinical Sample* (Silver Spring, MD: Association of Public Health Laboratories, 2011), retrieved December 4, 2012, from http://www.aphl.org/AboutAPHL/publications/Documents/PHPR_2011June_Algorithm-and-Guidelines-for-Responding-to-an-Incident-Involving-a-Suspicious-Non-Clinical-Sample.pdf.

The results of this research are intended for state public health agencies wishing to undertake framework standardization in order to increase biological terrorism (BT) preparedness levels and the DHS Science and Technology (S&T) Directorate in their ongoing efforts to support the emergency responder community through the implementation of national standards.

II. LITERATURE REVIEW

A. INTRODUCTION

The review, consisting of searches for literature pertaining to the bioresponse framework and bioterrorism (BT) preparedness, was conducted in two parts. Research was conducted using the Naval Postgraduate School's Dudley Knox Library[32] online resources and the Chemical, Biological, Radiological and Nuclear Defense Information Analysis Center (CBRNIAC).[33] The goal for the literature review was to establish a general understanding of the framework as it is presented in other published works and how it supports state/local BT preparedness. Some of the productive key words used to identify literature included "bioresponse," "bioresponse framework," "bioterrorism preparedness," "weapons of mass destruction (WMD) preparedness," and "CBRNE preparedness." Other key words and phrases were used but did not produce any significant literature. The collected literature was reviewed for additional publications in order to establish primary sources.

B. FRAMEWORK LITERATURE

The 2001 anthrax attacks were a catalyst event for bioterrorism preparedness and shaped the framework that we have today. The House of Representatives Subcommittee on National Security, Emerging Threats, and International Relations directed the GAO to assess the detection and testing activities associated with the anthrax mailings. The GAO, reporting in GAO-05-251, *Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results*, found that agencies did not use validated sample collection and testing methods.[34] Thus, there could be "little confidence in negative results."[35] The GAO report is significant because it established the need to validate five activities:

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[32] Dudley Knox Library is accessible at http://www.nps.edu/library/.

[33] Chemical, Biological, Radiological & Nuclear Defense Information Analysis Center is accessible at https://www.cbrniac.apgea.army.mil/Products/Inquiry/Pages/default.aspx

[34] GAO, *Anthrax Detection*.

[35] Ibid., 1.

1. sampling strategy development, followed by
2. sample collection,
3. transportation,
4. extraction, and
5. analysis of the samples.

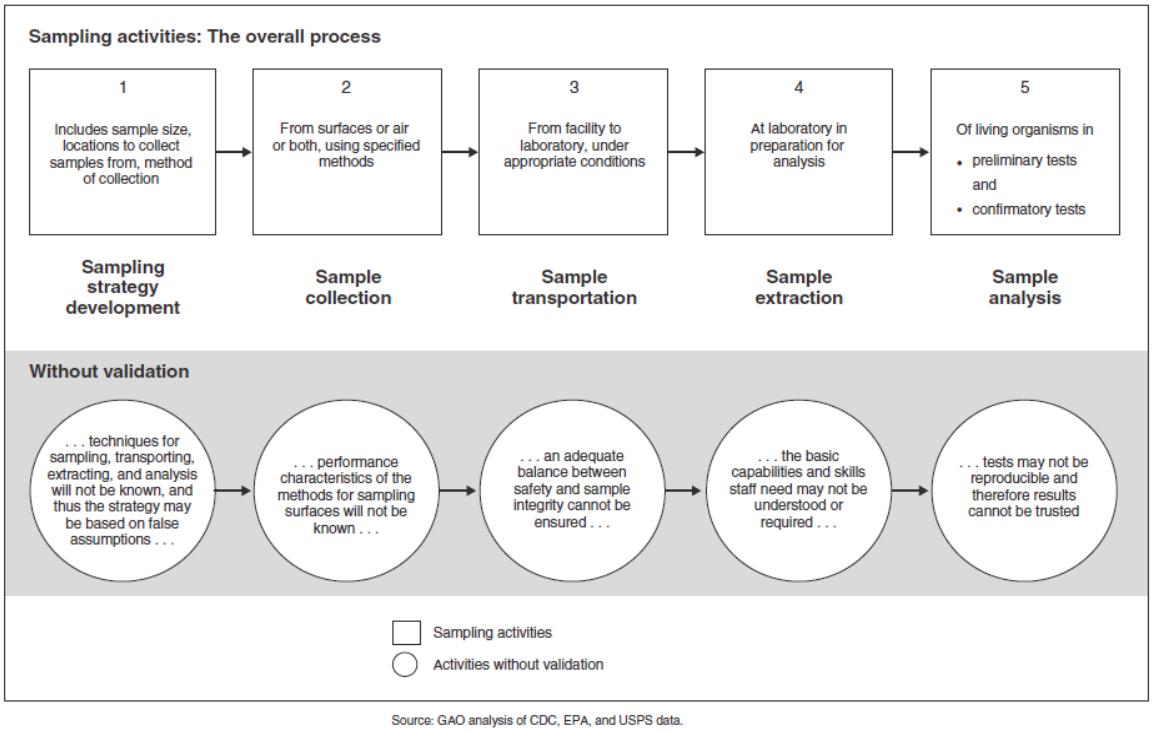

Figure 2. Lack of Validation Can Affect Indicidual Activites and the Overall Process[36]

The GAO used the tragic example of the Wallingford postal facility in Connecticut to illustrate the need to reduce false negatives. In the Wallingford example, the United States Postal Service (USPS) had sampled the mail facility and determined that it was cleared of contamination, only to trace back the cause of death of Ottilie Lundgren to mail that had been processed there.[37] Subsequent testing confirmed that, in fact, the facility was contaminated, which demonstrated the worst-case scenario

[36] Ibid., 61.

[37] Denise Grady, "A Nation Challenged: The Bioterror Threat-Mystery Death from Anthrax is Analyzed," *New York Times*, March 27, 2002, retrieved June 17, 2013, from http://www.nytimes.com/2002/03/27/us/a-nation-challenged-the-bioterror-threat-mystery-death-from-anthrax-is-analyzed.html?ref=ottiliewlundgren.

associated with false negatives. In bioterrorism response, false negatives are unacceptable. The GAO reported:

> Without validation, the sampling activities could have been based on false assumptions. For example, the lack of validated sample collection methods means that it is not known how many spores a particular method will collect from a surface and, thus, which method is appropriate for a given situation. Using an ineffective method or procedure could result in a finding of no contamination when in fact there is contamination—a false negative. Because the sampling methods are not validated, it is not known to what extent they will underestimate contamination. Thus, in the case of a negative result, agencies would have no sound basis for taking public health measures for the occupants of the contaminated facility.[38]

Limitations in detection technology were also reported in *GAO-08-180 First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas is Significantly Limited*. The reported stated that hand held assays (HHA), or an antigen-antibody complex based assay, do not have the sensitivity to detect low concentrations of threat agents that can still be considered hazardous.[39] Additionally, *GAO-08-180* also recognized a 2002 memorandum from the White House Office of Science and Technology Policy (OSTP) that recommended against emergency responders using field detection, such as HHA. The report quoted OSTP recommendations that were based from a joint evaluation study conducted with the CDC and FBI:

> Specifically, *Bacillus anthracis* detection thresholds for these devices are well above the minimum level that can infect personnel, and are not suitable for determining biological determinants of personnel, rooms, or pieces of equipment.[40]

The requirement to eliminate false negatives has been an ongoing theme in the development of the framework and was referenced in the FBI, DHS, HHS/CDC coordinated document *Guidance on Initial Responses to a Suspicious Letter / Container*

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[38] Ibid., 25.

[39] GAO, *First Responders' Ability to Detect*, 18.

[40] Ibid.

with a Potential Biological Threat.[41] The coordinated document describes the process to determine credible threat and the requirements for field screening. It was published in 2004 and represents the first interagency consensus on ConOp. The consensus in this document limits field screening when biothreat agents are suspected:

> Field safety screening should be limited to ruling out explosive devices, radiological materials, corrosive materials and volatile organic compounds. Currently, there are no definitive field tests for identifying biological agents. Additional field testing can mislead response efforts by providing incorrect or incomplete results, and destroy limited materials critical for definitive laboratory testing required to facilitate any appropriate public health and law enforcement response.[42]

Similar concerns regarding screening were also noted in other published documents. The Association of Public Health Laboratories' *APHL Model Practice: Algorithm and Guidelines for Responding to an Incident Involving a Suspicious Non-Clinical Sample* First Responder Algorithm diagram states in bold print "NO FIELD SCREENING FOR BIOLOGICAL THREAT AGENTS SHOULD OCCUR."[43] The APHL extrapolates this guidance in its position statement *Standardized Validation of Screening Kits and Devices for Use in the Field to Identify Hazardous Biological and Chemical Agents*:

> The Association of Public Health Laboratories (APHL) strongly opposes the use of biological and chemical agent detection kits and devices for field testing in the absence of performance standardization, field validation, and certified individuals trained in the application of these kits and devices. It is essential that a standardized validation, approval, and training process for these kits and devices be developed and implemented as soon as possible.[44]

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[41] Federal Bureau of Investigation, Department of Homeland Security, Department of Health and Human Services, and Center for Disease Control and Prevention [FBI, DHS, HHS, and CDC], *Guidance on Initial Response to a Suspicious Letter / Container with a Potential Biological* Threat (Washington, DC: Federal Bureau of Investigation, Department of Homeland Security, Department of Health and Human Services, and Center for Disease Control and Prevention, 2004), retrieved May 24, 2012, http://www.bt.cdc.gov/planning/pdf/suspicious-package-biothreat.pdf.

[42] Ibid., 6; John H. Marburger, "Purchase of Anthrax Detection Technologies," July 19, 2002, memorandum for Federal Mail Managers and First Responders to Federal Mail Centers, Executive Office of the President, Office of Science and Technology Policy, Washington, DC.

[43] Association of Public Health Laboratories, *Association of Public Health Laboratories Model*.

[44] Association of Public Health Laboratories, *Standardized Validation of Screening Kits*.

The literature does not support the use of screening for the purpose of characterization. Screening is limited to determining whether the material is safe to collect, not to characterize it for identification purposes. The literature limits the determination of credibility to such things as the presences of a threatening communication, reports of illness or suspicion gained through other observations and existing intelligence.[45] The process limits the role of technology and instead relies on an assessment of threat to determine overall risk. The literature may be contrary to the idea that risk determination is primarily the responsibility of the local HAZMAT team. In contrast, framework literature is more accepting of on-site characterization screening (also referred to as "biological assessment").[46] This "gap" in the framework is addressed in *ASTM E2770-10 Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent*:[47]

> **3.1.13** field screening, n—field measurements utilized early in the site assessment process to define and delineate the contaminants present, support tactical decision making and address operational safety measures. Field screening does not include measurements of biological properties, which is termed on-site biological assessments (see **3.1.20**).[48]

And:

> **3.1.20** on-site biological assessment, n—measurements of properties inherent to biological materials performed in the field using rapid, field based procedures and assays.[49]

ASTM E2770-10 does not recognize biothreat agent screening, but it does open the door for "on-site biological assessment."[50] This change was also marked by ASTM E2458-10, Standard Practices for Bulk Sample Collection and Swab Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Surfaces.[51] ASTM

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[45] FBI, DHS, HHS, and CDC, *Guidance on Initial Response to a Suspicious Letter*.

[46] ASTM International. *E2770-10: Standard Guide for Operational Guidelines*, 3.

[47] Ibid.

[48] Ibid.

[49] Ibid. 3.

[50] Ibid. 8.

[51] ASTM International, *E2458-10: Standard Practices for Bulk Sample Collection*.

E2458-10 is a sample standard that directs the sampler to split the sample at point of sample to provide material for off-site analysis and on-site analysis (PSAA).

In the development of a national framework these supporting documents have "space" for on-site biological assessments (PSAA and characterization screening), but as APHL has stated, that space requires "performance standardization, field validation, and certified individuals trained."[52] These concerns are voiced from APHL's role in representing the best interests of the state's public health laboratories and address the lack of a coherent quality assurance program. The concerns were addressed in the *Framework for a Biothreat Field Response Mission* Capability as part of the framework's five critical elements:[53] ConOp, certified training, field proficiency tests, sample handling standards, and validated assays set the foundation for reliable field-based results that can be useful in assessing hazard during the early hours of a response.

The *Framework for a Biothreat and Response Mission Capability* is an "umbrella" document that coordinates several other publications, such as ASTM E2770-10, ASTM E2458-10, and the FBI, DHS, HHS/CDC coordinated document. The document was created with interagency collaboration and reflects the same concerns referenced in the APHL algorithm.[54] The first element (ConOp), fourth (sample handling), and fifth (validated technology) critical elements have been accomplished. What has not been accomplished at the national level are training and certification standards (third element), and field proficiency testing (third element).

The requirement to implement the framework can be traced back to the 2010 *National Security Strategy*, where it was stated, "There is no greater danger to the Nation than a terrorist with a weapon of mass destruction," and then again in the President Barack Obama Administration's release of A National Strategy for CBRNE Standards.[55,56] The current literature does not define a strategy for implementing the

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[52] Association of Public Health Laboratories, *Standardized Validation of Screening Kits*.

[53] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability*, 3–4.

[54] Association of Public Health Laboratories, *Association of Public Health Laboratories Model*.

[55] White House, *National Security Strategy*, 4.

framework, but a theme is present that does lead to one. ASTM E2770-10 "Sections 6-Plans," "7-Training," and "8-Competency Assessment Exercises" provide the guidance necessary to establish a three-phased approach to implementation. Two of the three phases are also seen in the APHL position statement requirements of "field validation, and certified individuals trained."[57] A three-phased implementation strategy also supports a metric for determining biothreat response preparedness.

C. PREPAREDNESS LITERATURE

Measuring a state's preparedness to respond to a biothreat event is problematic because actual demonstration of preparedness is as rare as the events themselves. No national standard of performance exists and "peer-reviewed literature is not well represented" with regards to evaluating biothreat preparedness in the emergency responder community.[58] In a RAND issue paper by Fricker, Jacobson, and Davis *Measuring and Evaluating Local Preparedness for a Chemical or Biological Terrorist Attack*, it was found through an extensive survey of emergency responders that plans and exercises were considered to be the best metrics.[59] However, the Fricker, Jacobson, and Davis paper also identified that "quantifying preparedness for terrorism, by any measure, is elusive."[60] In another RAND article by Nelson, Lurie, and Wasserman, *Assessing Public Health Emergency Preparedness: Concepts, Tools, and Challenges*, a conceptual framework for assessment was described as, "Assessment: involves comparison between measures of actual performance and standards that describe ideal or desired

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[56] National Science and Technology Council Committee on Homeland and National Security, *A National Strategy for CBRNE Standards* (White House, National Science and Technology Council Committee on Homeland and National Security, 2011), 4, retrieved May 10, 2012, http://www.whitehouse.gov/sites/default/files/microsites/ostp/chns_cbrne_standards_final_24_aug_11.pdf

[57] Association of Public Health Laboratories, *Standardized Validation of Screening Kits*.

[58] Christopher Nelson, Nicole Lurie, Jeffrey Wasserman, "Assessing Public Health Emergency Preparedness: Concept, Tools, and Challenges," *Annual Review of Public Health*, vol. 28 (Santa Monica, CA: RAND, 2007), 1–18, retrieved May 10, 2012, from http://publhealth.annualreviews.org.

[59] Ronald Fricker, Jerry Jacobson, Lois Davis, *Measuring and Evaluating Local Preparedness for a Chemical or Biological Terrorist Attack* (Santa Monica, CA: RAND, 2002), 2, http://www.rand.org/pubs/issue_papers/IP217.html (accessed May 10, 2012).

[60] Ibid., 1.

performance."[61] The ASTM E2770-10 sections can be used to support a Nelson, Lurie, and Wasserman assessment framework: phase 1, training, and phase 3, plans, approach for "standards that describe ideal or desired performance," and a phase 2, exercises approach as "actual performance."

The literature indicates linking evidence-based preparedness to policy objectives has been elusive because performance metrics are not clearly defined. Nelson, Lurie, and Wasserman identified that without performance metrics it will be "difficult to assess the effectiveness of past investments, engage in continuous quality improvement of current efforts, or design and target future efforts."[62]

This is problematic when we consider the substantial investments in preparedness that have occurred since President Clinton issued *Presidential Decision Directive (PDD)-39, U.S. Policy on Combating Terrorism*.[63] Falkenrath describes the U.S. preparedness program from the 1990s up to 2001 in *Problems of Preparedness: U.S. Readiness for a Domestic Terrorist Attack*.[64] Furthermore, he captures a historical perspective that is useful in explaining the preparedness program that we have today and why we have some of the problems we do.[65] In addition, he observes that the "domestic program is unprecedented and highly complex, has grown very fast and confronts a range of public management challenges."[66]

The complexity derives, in part, from the fact that as a policy initiative, domestic preparedness is essentially a subset of U.S. counterterrorism policy, but in practice it is functionally related to disaster management. Most preparedness activities are closely

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[61] Nelson, Lurie, Wasserman, *Assessing Public Health Emergency Preparedness*, 1–18.

[62] Ibid., 2.

[63] Gregory D. Koblentz, "Overview of Federal Programs to Enhance State and Local Preparedness for Terrorism with Weapons of Mass Destruction" (BCISA Discussion Paper 2001-5) (Boston, MA Harvard University, 2001), 2, Belfer Center, retrieved May 5, 2012, from http://belfercenter.ksg.harvard.edu/files/overview_of_federal_programs.pdf; White House, *Presidential Decision Directive 39 Policy on Counterterrorism* (Washington, DC: White House, 1995), Federation of American Scientists, retrieved May 5, 2012, from http://www.fas.org/irp/offdocs/pdd39.htm.

[64] Richard Falkenrath, "Problems of Preparedness: U.S. Readiness for a Domestic Terrorist Attack," *International Security* 25, no. 4 (2001): 147–186.

[65] Ibid.

[66] Ibid., 148.

related to basic disaster management functions, such as training, acquiring special equipment, developing plans, and conducting exercises. However, because the program has emerged as a subset of counterterrorism policy, the agencies that implement it are largely segregated from preparedness activities. Historically, agencies have developed WMD response plans and initiatives separate from the Federal Response Plan, while policy development has been led by the White House, with little input from the Federal Emergency Management Agency (FEMA).[67] According to Falkenrath, this has resulted in limited interagency coordination and may be partly responsible for the lack of federal guidance on performing readiness evaluations.[68] This also explains why credibility assessments, which are primarily the responsibility of law enforcement (i.e., counter terrorism and prevention), are not a HAZMAT (domestic preparedness and consequence management) function.

Of interest to the implementation of the framework, under the 1996 Nunn-Lugar-Domenici legislation, Falkenrath observes that the:

> Secretary of Defense shall carry out a program to provide civilian personnel of Federal, State and local agencies with training and expert advice regarding emergency response to threatened use of a weapon of mass destruction or related material.[69]

At that time, Falkenrath observed that the Pentagon was hesitant to assume this role because it was viewed as something other than its "core mission of war fighting."[70] In 2013, as overseas operations wind down, the Department of Defense is seeking to define mission space for its CBRN enterprise that was largely built post-9/11. That mission space could include supporting civil authorities in implementation of the framework through training and exercises as originally envisioned under the Nunn-Lugar-Domenici legislation.[71]

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[67] Ibid., 160.

[68] Ibid. 171–172.

[69] Ibid., 162.

[70] Ibid., 162.

[71] Ibid. 163.

D. CONCLUSION

The national strategy clearly identifies the need to establish a national biothreat response framework. The framework is loosely defined in the DHS document *Framework for Biothreat Field Response Mission Capability* and ASTM E2770-10. The APHL document *Algorithm and Guidelines for Responding to an Incident Involving a Suspicious Non-Clinical Sample* provides a workable ConOp. The lack of on-site biological assessment, including sample characterization screening, represents a gap in the framework ConOp considering that validated technology is available (e.g., Response Biomedical Corporation's RAMP System).[72] Additionally, the literature does not provide guidance on implementation, but a theme is present that can be synthesized into a three-phased implementation model: phase 1, training; phase 2, exercises; and phase 3, plans.

The literature on biothreat preparedness identifies the lack of an evidence-based assessment program, but the literature can be synthesized to support the same three-phased implementation model. In the current fiscal crisis, the cost of implementation is going to be a hurdle that must be addressed up front. The literature establishes the concept that the Department of Defense CBRN enterprise is positioned and sufficiently resourced to play a significant role in the three-phased implementation model. Determining if the cost of a national framework is justified by the gains in local preparedness is going to be difficult. Framework metrics for evaluating preparedness do not exist and this represents a gap in our national doctrine.

[72] Bruce Harper and Mathew Robinson, Method Modification (2004.08) to Field Testing of Visible Powders on a Variety of Nonporous Environmental Surfaces: Filed Study, *Journal of AOAC International* 89, no. 6 (2006) retrieved June 22, 2012, http://responsebio.com/uploads/publications/Anthrax_-_Harper__Robinson_(Dugway)_2006.pdf; "Ramp System for Biodetection," FEMA Responder Knowledge Base, retrieved June 22, 2012, from https://www.rkb.us/contentdetail.cfm?content_id=87411.

III. RESEARCH

A. INTRODUCTION

Research was organized into two methods in order to:

1. analyze the state of framework adoption within a sample of state public health agencies,
2. and to deductively analyze the potential impact of improving the framework ConOp.

The purpose of the research is to produce an outcome that broadens the current understanding of the framework and its level of adoption, in order to offer up a recommended implementation model for use by state governments and DHS S&T.

1. APHL survey
    a. What is the current state of framework adoption at the state level?
2. Hypothetic-deductive framework analysis
    b. What is the national bioresponse framework?
    c. What is the framework implementation model?

B. APHL SURVEY

1. Methodology

An APHL survey was sent to all APHL member laboratories. Member laboratories are the state public health laboratories that are designated CDC Laboratory Response Network (LRN) members. LRN laboratories are the facilities that provide confirmatory analysis for unknown substances suspected of being a biological hazard. Participation was strictly on a voluntary basis. The survey was addressed to each laboratory's BT coordinators. BT coordinators have a unique vantage point within the ConOp that allows them to evaluate framework adoption activities. Recruitment occurred via an emailed survey description sent by APHL to all member laboratories with a link to an online questionnaire.

The online survey consisted of 27 questions distributed over three sections:

1. training,
2. competency and proficiency evaluation exercises, and
3. plans and guidance (Appendix).

Each section had a similar series of five questions utilizing a Likert item response format. The five topics used in each question series included:

ConOp (roles and responsibilities, field exercises and certification levels),

4. risk assessment,
5. presumptive analysis (PSAA),
6. sample collection, and
7. sample screening.

A Likert scale was used to assess the implementation level responses. The 15 Likert scale responses were calculated to determine a representative implementation average and then ranked.

Furthermore, one additional topic was used in each question series pertaining to collaboration with a list of possible response items. The other eight questions were a mix of open ended and yes/no responses allowing participants to elaborate on their implementation activities. Questions and response options were derived from ASTM E2770-10: Sections 6-Plans, 7-Training, and 8-Competency Assessment.[73]

2. Data Evidence

Out of 50 possible state public health laboratories, 27 BT coordinators completed the survey—a response rate of 54 percent. Participants were given the option not to answer a question, and participation varied from question to question. On average, 12 participants skipped questions in each of the sections, giving an overall response rate of 56 percent among the participating states. Some states indicated that they did not know the answer and thus were not factored into the response data, adjusting the response rate of participating states down to 45 percent. On average for any given question, 24.3 percent of the possible BT coordinators nationwide participated. Results were scored

[73] ASTM International. *E2770-10: Standard Guide for Operational Guidelines,* 5–6.

according to responder selection on a Likert scale with one as the lowest level of implementation and five as full implementation. Responses for open ended and collaboration questions were analyzed for content.

3. Survey Results

The survey results indicate that some implementation activity is occurring in each of the three implementation phases. Activity in any of the phases is significant because it indicates state implementation activity rather than federal. Table 1 displays the three section results (plans, training, and exercises) and their ranking based on the averaged responses of the section's questions. This was accomplished by totaling results for each question and dividing the total by the number of participants. The overall averages from each section were then calculated again and used to rank the categories from one to three, with one indicating the greatest level of activity.

Table 1. Response Results Chart

Category	Question	Averaged Response			Total Average	Rank
		Total Response Value	Number Of Respondents	Average		
Plans	Roles and Responsibilities	38/*n*13=2.923			2.4132	1
	Risk Assessment	22/*n*9=2.444				
	PSAA	13/*n*11=1.181				
	Sample Collection	27/*n*10=2.7				
	Sample Screen	31/*n*11=2.818				
Training	Certification Levels	9/*n*10=.9			2.125	2
	Risk Assessment	24/*n*11=2.182				
	PSAA	10/*n*5=2				
	Sample Collection	29/*n*11=2.636				
	Sample Screening	30/*n*11=2.727				
Responder Competency Exercise	Field Exercise	36/*n*10=3.6			2.0144	3
	Risk Assessment	16/*n* 8=2				
	PSAA	3/*n*8=.375				
	Sample Collection	20/*n*9=2.222				
	Sample Screening	15/*n*8=1.875				

Results of the analysis rank implementation as: 1) plans, 2) training and, 3) competency and proficiency evaluation exercises. Participation in question responses ranked similarly with plans, having a total of 54 responses, training 48, and exercises 43. Response participation was voluntary and reasons for opting out were not identified. A possible explanation may be that states with activity to report participated with greater frequency than those with no activity to report.

The rankings are consistent with the process order of the Federal Emergency Management Agency's (FEMA) "preparedness cycle" (Figure 3), which indicates greater activity earlier in the cycle.[74] Analysis of these findings indicates that conceptual ideas, such as plans and guidance are facilitating framework implementation with greater frequency than emergency responder activities such as exercises and training.

Figure 3. FEMA Preparedness Cycle Diagram[75]

Plans represent a community's potential to prepare for and provide a unified response to a hazardous event. FEMA describes planning as part of the national

[74] Federal Emergency Management Agency, *National Preparedness Cycle* (Washington, DC: Federal Emergency Management Agency, 2013), retrieved July 22, 2013, from http://www.fema.gov/national-preparedness-cycle.

[75] Ibid.

preparedness cycle as, "Strategic and operational planning establishes priorities, identifies expected levels of performance and capability requirements, provides the standard for assessing capabilities and helps stakeholders learn their roles."[76] Collaboration in the development of state plans and guidance is important to implementation because it is an indicator of the extent to which the framework ConOp has been implemented. The first question in the Plans Section established who within the state was collaborating on bio-response plans and guidance.

20. Is there collaboration between the public health laboratory and other agencies in the development of state bio-response plans or guidance for a first responder (i.e. HAZMAT teams) response to a suspicious substance event? If so, please check all that apply:

	Response Percent	Response Count
FBI WMD Coordinator	**72.2%**	**13**
National Guard Bureau Civil Support Team (CST)	66.7%	12
First responder community	66.7%	12
No state plans or guidance document	0.0%	0
No collaboration	11.1%	2
	Other (please specify)	6
	answered question	**18**
	skipped question	**9**

Figure 4. Question 20

Analysis of the responses (including "other") indicate that 14 states, or 77.8 percent (n = 18), identified collaboration with their FBI WMD coordinator. In addition, 13 states (66.7 percent) also indicated collaboration with their National Guard Civil Support Team (CST). In contrast to these federally resourced agencies, 12 states (66.7

[76] Ibid.

percent) identified collaboration with their first responder community. Only two states (11.1 percent) identified other agencies as write-ins, including the United States Postal Inspection Service (USPIS). Federally resourced agencies were collaborated with equally, or more, than with the local emergency responder community. Furthermore, three states (21.4 percent) identified no collaboration. The remaining five question results in the Plans Section indicate the order of implementation activity as: roles and responsibilities (2.923, n = 13), sample screening (2.818, n = 11), sample collection (2.7, n = 10), risk assessment (2.444, n = 9), and PSAA (1.181, n = 11). Therefore, results indicate that implementation activity with regard to the ConOp (roles and responsibilities) is reflected greater in plans than emergency responder actions such as sample collection and sample screening. The order of implementation for responder actions (screening, sample collection and risk assessment) was consistent with the Training Section. PSAA planning (1.181, n = 11) was ranked the lowest, which indicates some states have incorporated emergency responder results into their ConOp, but implementation is lagging behind other framework elements. This is significant to the ConOp because PSAA results may be considered disruptive if the state is not incorporating a QA program. Low PSAA implementation may indicate difficulty in adopting a QA program, altering an existing ConOp plan, or the absence of PSAA detection instruments in the field. Furthermore, additional inquiry into the reasons why PSAA is lagging is needed.

Training represents a community's ability to enhance its emergency responders with the knowledge, skills, and abilities needed to perform key tasks required by specific capabilities. In the FEMA *Preparedness Cycle*, training is "…based on information derived from the assessments, strategies, and plans developed in previous steps of the Preparedness Cycle."[77] Any training activity at the state level specific to framework implementation is significant because there is currently no coordinated national training curriculum for biothreat response.[78] Training programs, and specifically the presence of

[77] Ibid.

[78] There is no coordinated national training program in the U.S., although here are standards that provide guidance for the foundation of a training curriculum, including NFPA 472 and ASTM E2770.

certified training levels, are state initiatives. Training programs indicate a proactive investment from the state to standardize response activities and are strong indicator of future framework adoption. In addition, 45percent (*n* = 20) of the responding public health laboratories reported that their state has a first responder-training program for bioresponse, with two states indicating some level of certification.

As in the prior section, the first training question was asked in order to identify who is participating in training development. Collaboration is vital to implementation because of the impact it has on standardization across diverse agencies.

3. Is there collaboration in the development and delivery of the state's bio-response training between the public health laboratory and other organizations? Please check all that collaborate.

	Response Percent	Response Count
FBI WMD Coordinator	35.3%	6
National Guard Bureau Civil Support Team (CST)	**41.2%**	**7**
State Law Enforcement	0.0%	0
Local Law Enforcement	0.0%	0
Fire Department	0.0%	0
HAZMAT	17.6%	3
None	5.9%	1
	Other (please specify)	15
	answered question	**17**
	skipped question	**10**

Figure 5. Question 3

Using the "Other (please specify)" results combined with the listed results, responses to training collaboration indicate that the FBI coordinator was involved with

70.6 percent (n = 17) of the participating state laboratories, and the CST was involved with 76.5 percent. Emergency responders were collaborated with to a lesser extent: HazMat 58.8 percent, fire departments and local law enforcement 41.2 percent, and state law enforcement 46.2 percent.

The results indicate that states are primarily collaborating with federally resourced agencies instead of local emergency responders. These findings indicate opportunity for a national standardization effort led by the state public health laboratory in collaboration with the National Guard's CST program and the FBI. The other five question results in the Training Section indicate the order of implementation activity as: sample screening (2.727, n = 11), sample collection (2.636, n = 11), risk assessment (2.182, n = 11), psaa (2, n = 5), and certification (.9, n = 10). Certification was reported markedly lower than the other framework components. Training is occurring but states appear to be reluctant to assign certification levels. Reasons for this could be that states see little benefit due to a low prevalence of PSAA technology, or rejection by the emergency responder community. Of the five states that reported PSAA training in question, five only one reported having certification levels. It is unclear why certification levels are not part of state training and additional research should seek to establish the reasons why.

Sample screening training activity was higher than the other framework components, including PSAA. For example, 58.8 percent (n = 17) of the participating states indicated that they were training emergency responders on state developed screening protocols. In addition, 7.6 percent reported using the FBI-DHS-HHS/CDC coordinated document, and 11.8 percent reported using the *APHL Algorithm*. In contrast, 25 percent (n = 20) of the participating public health laboratories reported in question five that they were incorporating PSAA technology, such as PCR, into their emergency responder training programs. This is significant since there are no national standards regarding PSAA, and states are developing their own in the absence of national standards.

Exercises represent a community's ability to assess competency and proficiency and incorporate lessons learned into their existing plans. Because biothreat incidents involving actual pathogens are rare, exercises provide the next best opportunity to

evaluate preparedness.[79] FEMA describes exercises within the *National Preparedness Cycle* as "an objective assessment of gaps and shortfalls within plans, policies and procedures to address areas for improvement prior to a real-world incident."[80] Exercises are fundamental to implementation because they clarify roles and responsibilities. 11 states, or 55 percent (n = 20) reported that they are conducting functional exercises with their emergency responder community. As with the prior sections, the first question was designed to identify who is participating in exercises.

12. Are competency assessments of biothreat response operations conducted in collaboration with the state public health laboratory? Please check all that apply. This question is not asking if your state laboratory is assessing responder competency but rather if they are participating in a competency assessment program with other agencies, i.e. do you receive samples from the field during an exercise? Competency assessment includes proficiency of emergency response personnel in knowledge, skills, and abilities identified in the training program. An assessment can be an exercise, test, or drill.

	Response Percent	Response Count
FBI WMD Coordinator	11.1%	2
National Guard Bureau Civil Support Team (CST)	**61.1%**	**11**
First Responder Community (i.e. HAZMAT teams)	27.8%	5
Law Enforcement	16.7%	3
None	38.9%	7
	Other (please specify)	4
	answered question	**18**
	skipped question	**9**

Figure 6. Question 12

[79] Fricker, Jacobson, and Davis, *Measuring and Evaluating Local Preparedness*. 4.

[80] Federal Emergency Management Agency, *National Preparedness Cycle*.

Analysis of the responses (including "other") indicated that 11 states, or 61.1 percent (n = 18), are exercising with their CST. Other federally resourced agencies include the FBI (11.1 percent) and the USPIS (5.6 percent). States reported exercising with emergency responders (27.8 percent) and law enforcement (16.7 percent) to a lesser extent. Therefore, states that participated are reporting that they have established exercise relationships primarily with their CST, and to a lesser extent, their local emergency responder communities. Reasons for the reliance of CST exercise participation could be because of their role in facilitating exercises, their statewide response role vs. a specific county or municipality, or their utilization of PSAA results. Additional inquiry should be conducted in order to determine why CST are prominent in field exercises.

The remaining five question results in the Exercise Section indicate the order of implementation activity as: field exercises (3.6, n = 10), sample collection (2.222, n = 9), risk assessment (2, n = 8), sample screening (1.875, n = 8), and PSAA (.375 n = 8). The order of the emergency responder activities changed with screening dropping from the highest to the lowest. PSAA remained last in order but also had a significant drop in reported activity. PSAA and screening represent detection technology and given the results it is concluded that more effort needs to occur in order to evaluate proficiency and the impact of on-site detection to the ConOp. Reasons for the low reporting could be related to the lack of challenge material availability for testing screening and PSAA results. The reasons for not exercising technology should be identified because without evaluating the testing process between field and LRN states will not be able to measure preparedness. Exercises should not end once the sample is collected, they should continue to include LRN results in order to evaluate the entire ConOp and testing algorithm.

C. SURVEY ANALYSIS

Survey results indicate public health activities support response framework implementation with activity in all three phases. BT coordinators reported that they are collaborating with their CST and FBI WMD coordinators in all three phases. Federal collaboration at the state level indicates a common link to all APHL laboratories, since each state has a CST and FBI WMD coordinator. The CST and FBI are federally

resourced and have standardized methods and procedures. Local collaboration was also reported but to a lesser degree, indicating a potential for future effort.

The analysis of PSAA implementation data across the three categories of plans, training and exercises was at a lower level (1.185) than all other components of the framework. PSAA also had the lowest survey participation rate (n = 24), which may indicate that states with implementation activity participated in greater frequency than those with no activity. In comparison, sample screening had a higher level of implementation (2.473) and survey participation (n = 30). These findings indicate that states maybe implementing screening with greater frequency than PSAA. Based on these results, it is probable that more states will need technology to support screening activities other than PSAA. It was unclear from the survey if emergency responders were conducting biological characterization, or just safety screening.

Both lines of questioning pertain to technology and have significant impact on a state's ConOp. Several states reported that they rely on their CST for PSAA, which is an indication that the concept of on-site biological assessment is beneficial. One state reported the use of lateral flow immunoassays (referred to as a hand held assay [HHA]) with PCR in progress. HHA results are used to screen samples and this state's response may characterize a larger trend amongst the states to implement screening in greater frequency than PSAA. Reasons for this suspected trend may include characterization preference over PSAA due to lower QA requirements, lower cost of screening technology, or the impact of results on the ConOp.

State training indicates a higher occurrence of screening than PSAA, but five states reported that they had incorporated PSAA technologies into their state training programs. Without national training standards, we can expect that states will develop their own, resulting in significant variation from one state to the next. While training programs need to be state specific, the utilization of technology and the development of analytical methods to support its use should not. PSAA standardization should occur at the national level. State activity in this component of the framework indicates a potential for the standardization window to close in these states if a national training curriculum is not developed quickly.

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IV. HYPOTHETIC-DEDUCTION FRAMEWORK ANALYSIS

A. METHODOLOGY

Hypothetic-deduction is a method of research in which a hypothetical framework based on observations is proposed and then tested by consequences from the model.[81] In this analysis, I will develop a hypothetical bioresponse framework based on observations from the CST program. Aspects from the CST program can be used to develop an improved framework for the emergency responder community. This analysis will help future implementation efforts by offering a suggested framework model that has significant improvements over the current one.

B. HYPOTHESIS

Implementation can be successful with a modified framework that incorporates on-site biological assessment, including sample characterization screening and PSAA. The use of technology in the hazard assessment and threat analysis ConOp will not be disruptive because results will be considered reliable. The modified framework will be modeled after the successful CST program, which includes a workable quality assurance program and centralized logistical support.

C. DATA EVIDENCE

1. What the Current Framework is Missing

The field based triage framework described in the *APHL Algorithm*[82] and ASTM E2770-10[83] quickly seeks to determine the level of risk associated with a suspicious substance. Risk is determined by conducting a threat and hazard assessment; then the level of risk is used to guide responder actions during a response. The triage ConOp

[81] *Academic Dictionaries and Encyclopedias*, s.v. hypothetic deduction, last modified 2013, retrieved May 22, 2013, from http://universalium.academic.ru/130304/hypothetico-deductive_method.

[82] Association of Public Health Laboratories, *Association of Public Health Laboratories Model*.

[83] ASTM International. *E2770-10: Standard Guide for Operational Guidelines*.

works to reduce consequences by accurately identifying true acts of bioterrorism while reducing the impact of copycat events.

After the anthrax attacks of 2001, detection technology in the field was not considered suitable for use by emergency responders. False positives and negatives meant that results were unreliable and thus unusable during the hazard assessment and threat analysis process. From the start, the framework ConOp emerged relying on judgments derived from conducting a threat evaluation. The threat was determined by the presence of threating communications, dissemination devices, victims presenting with signs and symptoms, or intelligence warning of an impending event. The national guidance was biased heavily towards the role of a law enforcement threat evaluation and against the use of technology by a trained HAZMAT technician. The bias was reflected in the guidance documents and described during the literature review.

The literature is contradictory at best, and it is lacking in any clear standard with regard to on-site biological assessment or PSAA. Space has been set aside within the ConOp literature for "jurisdictions choosing to integrate on-site assessment into response procedures…," but the literature does not rely on "on-site assessment."[84] Instead, the literature promotes the importance of conducting a threat assessment. This gap in the hazard assessment and threat analysis process can be problematic to the overall determination of risk. The literature review established that the CDC or the FBI do not accept on-site biological assessment results because they "…can mislead response efforts by providing incorrect or incomplete results, and destroy limited materials critical for definitive laboratory testing."[85] Instead, the threat assessment—which is fundamentally a judgment call made by law enforcement and not certified HAZMAT technicians—is the determining factor in risk. This assumption only works if one accepts that judgment calls by law enforcement are less likely to be "incorrect or incomplete" than screening and testing results by a certified HAZMAT team.

[84] Ibid., 8.

[85] FBI, DHS, HHS, and CDC, *Guidance on Initial Response to a Suspicious Letter*, 6.

In practice, doctrine often times lags behind innovation and trend. HAZMAT teams are using technology to support their hazard assessments; the results can be considered disruptive to the ConOp if they are rejected by other responding agencies, such as the FBI. These results can also be disruptive if they are incorrect, and without validated assays, certified training, or quality assurance measures, such as proficiency testing, the accuracy of the results cannot be gauged.

2. CST Comparison

The Civil Support Team program came online during the 2001 anthrax attacks with 10 original teams located to respond within each FEMA region. Each team consists of 22 full-time personnel encompassing 14 career specialties. Their mission is to respond to requests by civil authorities during a CBRN event. The teams have unique capabilities, such as a mobile laboratory, that make them a valuable resource to their local communities.[86] The initial success of the CST program saw a rapid expansion from the original 10 teams to 57, one for each state and territory, with several states fielding two teams. CSTs are federally resourced and standardized.

In contrast to their local emergency responder counterparts, CSTs are funded to train, equip, and maintain readiness at a level that is unachievable by most local agencies. Since the certification of the original 10 teams in 2001, the CST program has established a robust quality assurance program that ensures consistent and accurate on-site biological assessment and PSAA results. CST results are accepted by other responding agencies and are not considered disruptive to the hazard assessment and threat analysis process. The components of the CST program that directly support the credibility of field results will be used to develop an improved hypothetical framework.

CST survey sections are equipped not only to conduct safety screenings for radiological, explosive, and volatile hazards, but the teams can also conduct base characterization at point of sample. This unique capability is accepted by the LRN as one

[86] Headquarters Department of the Army, *Weapons of Mass Destruction-Civil Support Team Operations* (FM3-11.22) (Headquarters Department of the Army, 2007), retrieved August 13, 2013, from http://armypubs.army.mil/doctrine/DR_pubs/dr_a/pdf/fm3_11x22.pdf.

of the CST's primary assets. [87] Characterization is accomplished through the use of technology, such as lateral flow immunoassays, for detecting select agents. The assays cannot be used to clear a sample for biological hazard, but they can be significant in terms of characterizing it as a biological hazard. The analytical laboratory system (ALS), a mobile laboratory with PCR capability and additional immunoassay capability, accomplishes PSAA testing of a sample. On-site biological assessment not only feeds the hazard assessment process, but also helps in determining an analytical strategy. ALS PSAA results are considered reliable, but an LRN laboratory must accomplish final confirmation.[88]

The CST program has made significant investments in ensuring that screening and testing results are accurate and consistent by obtaining ISO 17025 accreditation.[89] The CST program partnered with Signature Science to develop a quality management system that met the requirements of the ISO 17025 standard in the context of the unique CST mission.[90] Components of the quality assurance program included standardized training, validated methods and procedures, external evaluations, and third-party delivered proficiency tests. The quality management system established the program's credibility and bolstered the defensibility of the analytical data. The end result of the effort is a state level asset that can screen and test samples in the field in order to provide a fully developed hazard assessment within a matter of hours after arriving on scene.

The CST is a unique asset that requires robust logistical support. Another significant component of the quality assurance program is ensuring that equipment is operating within prescribed parameters, supplies are up to date, and deficient equipment is replaced before it can affect the quality of a result. Without a robust and centralized logistics system, the CST program would not be able maintain ISO 17025 accreditation.

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[87] CDC and National Guard, *The Role of the Civil Support Team*, 1.

[88] Ibid., 12–13.

[89] ISO/IEC Resource Center, "Accreditation," ISO/IEC Resource Center, retrieved July 22, 2013, from http://www.isoiec17025.com/wst_page4.html.

[90] M. Isbell, "ISO 17025 Accreditation of the U.S. National Guard Weapons of Mass Destruction: Civil Support Team Mobile Laboratory," poster presentation at National Environmental Monitoring Conference, Austin, Texas, 2013, retrieved June 14, 2013, from http://nemc.us/meeting/2013/load_abstract.php?id=169.

3. Hypothetical Framework

An improved framework, as envisioned in the *Framework for a Biothreat Mission Capability* and required by the *National Strategy for CBRNE Standards*, will utilize innovative technology to raise local preparedness. Drawing from the CST program example, a framework model can be developed that is specific for emergency responders. The improved framework will:

1. utilize detection technology to support on-site biological assessment and PSAA testing at point of sample,
2. adapt the ConOp to use the technology to improve the hazard assessment process,
3. strengthen the credibility and accuracy of results through a responder specific quality assurance program, and
4. increase mission readiness through a centralized logistics program. These four improvements will increase local preparedness and improve the triage process of determining the risk associated with a suspicious substance event.

An improved framework would deploy technology to support the hazard assessment process. Detection technology can be categorized as either on-site biological assessment or PSAA, which defines how the results will support the ConOp. The difference between on-site biological assessment (i.e., screening and PSAA testing) is the potential for false negative results. False results can occur because the technology does not have the specificity or sensitivity to accurately detect, or because the technology is not utilized effectively. Therefore, technology should be validated in the context of the framework ConOp.

Examples of detection technology for on-site biological assessment include pH and protein detection (i.e., BioCheck[91]), fluorescence staining (e.g., Prime Alert)[92] ATP detection (i.e., GenPrime Prime Alert Kit[93]), and lateral flow immunoassays (BioThreat

[91] BioCheck, "20/20Gene Systems," BioCheck, retrieved May 10, 2012, from http://biocheckinfo.com/.

[92] Smiths Detection, "Prime Alert," Smiths Detection, retrieved August 13, 2013, from http://www.smithsdetection.com/en/biological-agents-detection/114-biological-agents-detection/prime-alert.html.

[93] GenPrime, "Prime Alert," GenPrime, retrieved May 10, 2012, from http://www.genprime.com/products_primealert.asp.

Alert[94]). Other characterization technologies include Fourier transform infrared (FTIR) spectroscopy (e.g., Smith's Detection HazMatID[95]). FTIR can identify protein and the presence of silica in powder, which is used as aerosolizing agent.[96] PSAA testing can be supported with technology that was once the domain of the fixed laboratory. Real-time PCR platforms (such as the BioFire Diagnostics RAZOR,[97] or FilmArray,[98] Smiths Detection BioSeeq,[99] Tetracore T-COR4,[100] or GeneReach USA POCKIT[101]) are capable of reducing the occurrence of false negative results to a level that should be acceptable to the FBI and CDC. PCR results, as demonstrated by the CST program[102], can be factored into the risk assessment process.

Although a number of on-site biological assessment and PSAA detection technologies are commercially available to first responders, few of them have undergone rigorous third party evaluation.[103] For a detailed review of available technologies for field use, see the Pacific Northwest National Laboratory (PNNL) report *Biodetection*

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94 Tetracore, "BioThreat Alert," Tetracore, retrieved May 10, 2013, from http://www.tetracore.com/bio-warfare/index.html.

95 *HazMat ID*. Smiths Detection http://www.smithsdetection.com/hazmatid360.php (accessed May 10, 2013).

96 BioFire Diagnostics Inc., "Biologic Field Identification," Armed Forces International, last modified June 7, 2009, retrieved May 10, 2013, from http://www.armedforces-int.com/article/biological-field-identification.html.

97 BioFire Diagnostics Inc., "Razor," BioFire Diagnostics Inc., retrieved May 10, 2013, http://www.biofiredx.com/RAZOREX/.

98 BioFire Diagnostics Inc., "FilmArray," BioFire Diagnostics Inc., retrieved May 10, 2013, from http://www.filmarray.com/

99 Smiths Detection, "BioSeeq." Smiths Detection, retrieved May 10, 2013, from http://www.smithsdetection.com/Bio-Seeq_PLUS.php.

100 Tetracore, "T-COR4," Tetracore, retrieved May 10, 2013, from http://www.tetracore.com/t-cor/index.html.

101 *POCKIT*. GeneReach USA, retrieved May 10, 2013, from http://www.genereach-us.com/product.php?a_id=1003&b_id=1004&id=114 (accessed May 10, 2013)

102 Federal Bureau of Investigation, "FBI Field Divisions and National Guard Civil Support Teams," memorandum of agreement (electronic communication 66F-HQ-A1430160, serial 153), January 2003; Association of Public Health Laboratories, *Association of Public Health Laboratories Model*, 9; CDC and National Guard, *The Role of the Civil Support Team*, 2.

103 Mary Wade, Mark Campbell, James Rogers, Burt Coursey, Kikoli Niyogi, Jennifer Coughlin, and Peter Emanuel, *Evaluation of an Inexpensive Field Test for Ruling out the Presence of Biological Threat Agents in Suspicious Powders* (ECBC-TR-459) (Edgewood Maryland, Edgewood Chemical Biological Center, 2006), 1.

Technologies for First Responders (PNNL-21713).[104] An improved framework must have validated assays in order to integrate the technology into the existing ConOp. Most handheld detection will not be suitable for PSAA due to issues of low sensitivity, cross-reactivity with environmental agents, and user error in interpreting results.[105]

If technologies undergo a third party evaluation, such as the stakeholder panel on agent assays (SPADA), and their performance potential is acceptable for the ConOp and the appropriate assay level (e.g. on-site biological assessment, PSAA), then the results should be factored into the hazard assessment in order to support the risk assessment process as defined in ASTM E2770-10 Section 10.[106] Detection technology is capable of enhancing the hazard assessment process beyond simple judgment calls made by law enforcement regarding threat. Technology can support the hazard assessment process so that it can be used to triage events during sample surge. Significant limitations to hand held detection for the purpose of characterization mean that results should only be considered in the absence of confirmatory results from an LRN laboratory, and should be used to elevate risk, not reduce it.

In contrast, presumptive testing results can be used to make PSAA decisions because the technology is capable of reducing the issues associated with field detection such as sensitivity and specificity. PSAA results should only be used in the absence of confirmatory results by an LRN laboratory; limited decisions can be made regarding risk to the immediate public, such as evacuating or determining decontamination strategies. The accuracy and credibility of the results must be determined prior to an event, and a robust quality assurance program, as per ASTM E2770-10 Section 8,[107] should include:

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104 Pacific Northwest National Laboratory, "Biodetection Technologies for First Responders" (PNNL-21713), (Richland, WA: Pacific Northwest National Laboratory, 2012), retrieved June 24, 2013, from http://www.pnnl.gov/nationalsecurity/technical/chemical_biological/Biodetection_Technologies_for_First_Responders.pdf.

105 "Preliminary Findings on the Evaluation of Hand-Held Immunoassays for *Bacillus anthracis* and *Yersinia pestis*," *Forensic Science Communications* 5 no 1 (2003) retrieved June 12, 2013, from http://www.fbi.gov/about-us/lab/forensic-science-communications/fsc/jan2003/fsru.htm; Carrie Poore, Paul Clark, and Peter Emanuel, "An Evaluation of Suspicious Powder Screening Tools for First Responders," *Journal of Hazardous Materials* 172 (2009): 565.

106 ASTM International. *E2770-10: Standard Guide for Operational Guidelines*, 7.

107 Ibid., 6.

standardized training, proficiency panels and annual field exercises in collaboration with the state's LRN laboratory and FBI WMD coordinator.

Additio*nal components of quality assurance that are not specified in the ASTM E2770-10 are drawn* from the CST program example and include a centralized logistics program with centralized oversight. PSAA testing, such as PCR platforms, requires costs well beyond the initial purchase. Local agencies will need support for their reagents and maintenance. If not, supplies that affect the quality of a result, such as reagents, will not be standardized. In addition, maintenance should be centralized and defective equipment should be exchanged for working equipment in order to maintain mission readiness. It would be a mistake to allow local agencies to purchase PCR platforms through a federal grant for a one-time purchase with no thought as to maintaining it. The detection platforms should be DHS property and issued to a local agency that has a demonstrated need, agree to participation in a quality assurance program, and demonstrate proficiency through externally evaluated functional exercises conducted in conjunction with the LRN and FBI.

4. Framework Consequences

Because of home rule, the biothreat framework must be flexible to meet the local requirements of the adopting state. Some components of the framework—such as the development of standards, the oversight of a quality assurance program, and the management of a centralized logistical support program—need to be national initiatives. Additionally, adoption must be voluntary since the framework also resides at the community and state levels. Components that are state initiatives should include training programs that incorporate national standards such as ASTM E-2458-10, functional exercises that incorporate competency and proficiency evaluations, and developing state plans and guidance documents that incorporate the framework ConOp and national standards, such as ASTM E2770-10. Framework implementation and the eventual maintenance will require federal funding streams, interagency cooperation, and clear guidance regarding responsibilities between the federal and state initiatives.

The consequences of using technology to support on-site biological assessment and PSAA testing include increased demands for the development of performance standards. Since the 2001 anthrax attacks, there has been a proliferation in the development and fielding of detectors that screen and test for the presence of biological agents.[108] Local agencies have limited means to verify if the detectors work as described, since they lack the ability to validate performance. Validated assays, the fifth critical framework element in the *Framework for a Biothreat Field Response Mission Capability* document,[109] addresses this consequence. There are two sub-elements that are necessary to achieve validated assays: performance specification standards and testing and certification. The framework document recommended that DHS continues to fund the established SPADA process to develop performance standards and that DHS use third party laboratories to test and certify assays in conjunction with the vendor in order to share costs.

The consequences of integrating on-site biological assessment and PSAA testing results into the ConOp to support the risk assessment process will require interagency consensus. Agencies will have to revise their guidance to emergency responders, such as the FBI, DHS, HHS, CDC coordinated document.[110] Getting interagency consensus on guidance will be difficult, but should not delay implementation. DHS will need to take the lead in establishing consensus, which can be argued is in support of the White House's *National Strategy for CBRNE Standards* Goal 4: "Promote enduring CBRNE standard operating procedures for Federal, State, local, and tribal use to improve National preparedness and response."[111]

Consequences of adopting a quality assurance program for emergency responder accreditation include the oversight and operation of the program. State governments will most likely not have the capability or resources to conduct a program themselves.

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[108] Peter Emanuel and Matthew Caples, *Chemical, Biological, Radiological Technology Survey* (Ft. Belvoir, VA: Defense Threat Reduction Agency, 2011), retrieved May 10, 2012, from https://www.rkb.us/contentdetail.cfm?content_id=262170.

[109] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability*.

[110] FBI, DHS, HHS, and CDC, *Guidance on Initial Response to a Suspicious Letter*.

[111] Department of Homeland Security, *A National Strategy for CBRNE Standards*, 13.

Therefore, the program should be administered by a third-party, with oversight being conducted by the LRN. The quality assurance program will need to be tailored for the emergency responder community; a key component of the program is the ASTM E2770-10 requirement to conduct annual proficiency test exercises in conjunction with the FBI and LRN.[112]

Field proficiency evaluations will require the development of challenge material (biological agents that can be detected) that does not pose a contamination threat to the public or responder equipment. Challenge materials for use in a traditional laboratory are usually attenuated versions of the pathogenic agent that the assay is designed to detect. Their use outside of a laboratory facility will require significant safety controls and oversight in order to avoid unintentional exposure or contamination of equipment and personal protection equipment (PPE). This was one of the major findings of the Operation Vigilant Sample (OVS) exercises, which used gamma irradiated sterne (*B. anthraces*) spores as the exercise challenge material.

The use of attenuated agents can lead to the contamination of responder equipment with several of the same molecular markers that can be detected by PCR at the LRN during a real world response. Therefore, field exercises should use a safe challenge material, such as *Saccharomyces cerevisiae* (yeast). Yeast assays are being developed by National Institute of Standards and Technology (NIST) to support field exercises. The implication of using something other than the agent that the assays are designed to detect is that the test is no longer determining proficiency. A new quality assurance approach is needed for evaluation that is appropriate for field-testing. Yeast challenge material will establish "confidence" in the ability of the operator to operate the detection system in a field setting; however, true proficiency determinations may have to be conducted in a laboratory setting.[113] Standards are under development by NIST that will establish the difference between traditional proficiency tests and the new confidence tests.

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[112] ASTM International. *E2770-10: Standard Guide for Operational Guidelines*, 6.

[113] Confidence test refers to the use of a safe alternative, such as yeast, to an attenuated select agent, such as the Sterne strain of anthrax. The use of an assay to detect an agent that the assay was not designed for means that results cannot be used to determine proficiency as commonly understood by certified laboratories. Instead, results indicate general confidence in end user competency and detector accuracy.

Another consequence of requiring a quality assurance program is the substantial logistical support that will be required to sustain it. A centralized logistical support program that maintains readiness will not be practical at the state level. Standardization of the quality assurance program will also require standardized logistics. DHS will need to oversee this program in order to ensure that participating states do not run out of approved supplies. The program can be outsourced to a commercial vendor who specializes in laboratory logistics.

Choosing to use a state's National Guard CST instead of developing local capability will leave states vulnerable during sample surge. CST teams provide unique capabilities to assist local authorities when they have a gap during response operations, but a CST should not replace or duplicate state capabilities. Emergency responders are the state's first line response assets and should be supported by framework implementation. If states choose to rely on CST capability instead of developing their own emergency responders' capability they may unintentionally undermine the efforts of local emergency agencies to modernize. Technology that was once the domain of the laboratory and specialized military units is now available to the emergency responder community and therefore should be supported by the five critical framework elements. The APHL survey results indicate some states are starting to adjust their plans and training to incorporate new technology. The consequences of not implementing a national framework mean federal and state governments run the risk of lagging behind the emergence of technology.

D. RESEARCH SUMMARY

The adoption of the framework is not complete, although some effort is currently underway. Implementation activities are best represented at the state level when they involve plans and guidance versus specific responder tasks such as training and exercising. Collaboration between the states' public health LRN laboratories, their CST, and FBI WMD coordinators has been reported, indicating that standardization between these agencies is possible. Additional effort is needed in determining what components of the framework are acceptable at the state level. Future efforts should include establishing

an expert panel of state representatives in order to form a consensus on what practices best support implementation.

A proposed framework modeled after the CST quality assurance program's ISO 17025 accreditation would significantly improve preparedness at the local level. The improved framework would:

1. utilize detection technology to support on-site biological assessment and PSAA testing at point of sample,
2. adapt the ConOp to use the technology to improve the hazard assessment process,
3. strengthen the credibility and accuracy of results through a responder specific quality assurance program, and
4. increase mission readiness through a centralized logistics program.

These four improvements will increase local preparedness by improving the triage process that determines risk associated with a suspicious substance event.

V. CONCLUSION

A. INTRODUCTION

The need for a national response framework is driven by the emergence of new technology and its incorporation into local response operations. The impact of innovative technology has the potential to disrupt unless it is fully supported by the critical elements of the biothreat response framework. Since 2001, the country has experienced a surge of suspicious substance events. The 2013 ricin mailings demonstrate that this trend is far from over.[114] Local emergency responders such as police, fire fighters, emergency medical services, HAZMAT technicians, and bomb squads all need detection technology. Detection capability is needed to not only ensure responder safety but to also conduct field assessments in support of the hazard assessment and threat analysis process. In the Defense Threat Reduction Agency (DTRA) 2011 *Chemical Biological Radiological Survey*, 282 devices were reviewed with 198 being specific to biological detection.[115] The impact of technology promises increased capability, but technology can also lead to a false sense of capability if used inappropriately. Communities are now confronted with a complex array of technical questions regarding the availability of new detectors such as, "does this equipment work as described?"; "can we operate it correctly?"; and "what do I do with the results?" The five critical elements of the national *Framework for a Biothreat and Response Mission Capability* can be used to answer these questions. The five critical elements can also build confidence in results so the threat assessment and hazard analysis process can be better supported.[116]

In the United States, the legislative authority granted to local governments varies by state, affecting how emergency response operations are conducted. In one community, a response may be led by public safety, and in another, that role maybe assigned to a law

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[114] "FBI Response to Reports of Suspicious Letters Received at Mail Facilities," Federal Bureau of Investigation National Press Office, April 17, 2013, retrieved May 2, 2013, from http://www.fbi.gov/news/pressrel/press-releases/fbi-response-to-reports-of-suspicious-letters-received-at-mail-facilities

[115] Emanuel and Caples, *Chemical, Biological, Radiological Technology Survey*, 5.

[116] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability*.

enforcement entity. The status of biothreat response at the community level is heterogeneous, with significant variation due to factors such as home rule,[117] population, geography, funding, and urban sprawl. These factors set priorities and result in differences between communities. Implementing a national framework therefore must include local adaptation as well as national standards.

The EMS system emerged in the late 1960s with state and local governments taking the lead in program development and system design.[118] Like the EMS example, the bioresponse framework will emerge when state and local governments take the lead. The federal government will be responsible for key aspects of the framework, but the work of implementation—and the eventual quality assurance program and system design—will be created based on the needs and capabilities of local communities. The lesson learned from the EMS example is that at its core, response is local, so variation in system configurations is to be expected. Despite variation, robust standardization regarding the quality assurance program must be implemented if results are to be consistent and reliable.

B. WHAT IS THE CURRENT STATE OF FRAMEWORK ADOPTION AT THE STATE LEVEL?

It is difficult to assess the extent of framework adoption at the community level since implementation has been largely independent of federal support. The APHL survey indicates local public health laboratories have implemented some components of the framework, but more needs to be accomplished. Framework adoption is possible, given the collaboration findings that show public health laboratories have working relationships between their CST teams and FBI WMD coordinators. In order to comply with *Presidential Policy Directive / PPD-8: National Preparedness*,[119] implementation

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[117] Kenneth Vanlandingham, "Municipal Home Rule in the United States," *William and Marry Law Review* 10, no. 2 (1968): 269.

[118] Ellen MacKenzie and Anthony Carlini, *Configurations of EMS Systems: A Pilot Study* (Baltimore, MD: Johns Hopkins Bloomberg School of Public Health, 2008), retrieved April 12, 2013, from http://www.ems.gov/pdf/810911.pdf.

[119] Department of Homeland Security, *Presidential Policy Directive / PPD-8: National Preparedness* (Washington, DC: Department of Homeland Security, 2011), retrieved July 24, 2013, from http://www.dhs.gov/presidential-policy-directive-8-national-preparedness.

activities should be undertaken in conjunction with NGB CST program, CDC LRN, and the FBI. These agencies represent a common response element in every state and are a ready-made mechanism for national standardization. Additionally, more work is still needed to incorporate emergency responder coordination in training and planning. It is recommended that state governments and public laboratories reach out to their responder communities to develop framework adoption practices.

State public health laboratories did indicate some activity regarding PSAA detection technology, while other laboratories indicated an interest to move in that direction. On-site biological assessment and PSAA testing in the field are becoming more prolific; there is a window of opportunity to establish the basis for a standardized quality assurance program before "next generation" detection becomes "today's detection" technology. It is recommended that states survey their responder communities in order to measure the impact that new technology is having on the response ConOp. Findings should be used to adjust state response plans and training programs and justify a quality assurance program if one becomes necessary.

In the absence of national training standards, almost half of the states surveyed indicated they are actively developing their own. Like the EMS example, training actively at the state level is an indication that states are capable of developing their own programs to include certification levels. Diversity in state training programs also indicates a clear need for national training guidance in order to support state program development. Additionally, PPD8 recognizes the need for national response capabilities and a coordinated national biothreat response training curricula is essential. A national curriculum would allow states to build off of their existing local capabilities and encourage state led training initiatives based on their unique jurisdictional needs.

Additionally, national guidance and standards are not always adopted. This was observed with 58.8 percent of the states reporting that they use state developed sample screening protocols instead of the FBI, DHS, HHS/CDC coordinated document or the *APHL Algorithm*. Although this finding is limited to those who participated in the survey, it may indicate a need for DHS to communicate standards more effectively at the state level.

C. WHAT IS THE NATIONAL BIORESPONSE FRAMEWORK?

A national bioresponse framework is defined by the five critical elements found in the *Framework for a Biothreat and Response Mission Capability* document. Progress has been made in establishing each of the elements, but some gaps were identified requiring adoption of CST specific practices.

A workable ConOp is defined in the mutually supporting framework documents. APHL describes the ConOp in the *APHL Model Practice: Algorithm and Guidelines for Responding to an Incident Involving a Suspicious Non-Clinical Sample* document,[120] and DHS describes it in *AST E2770-10 Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent*.[121] The documents are sufficient in scope and detail to allow local and state governments to incorporate the guidance into their plans and standard operation procedures (SOP). A state's ConOp should take into account on-site biological assessment and PSAA testing results. On-site biological assessment results can support the hazard assessment and threat analysis process in determining risk. Public safety actions based on on-site biological assessment results should only be used to make ascending and lateral safety decisions. For example, an on-site biological assessment result can identify the need to upgrade personal protection equipment (PPE) level (ascending) or justify changing the type of decontamination solution used during decontamination (lateral), but on-site biological assessment results cannot be used to lower PPE levels.

In contrast, PSAA detection supports the threat assessment and hazard analysis process; in limited situations, results can be used to justify descending safety actions, such as reducing the level of PPE. On-site biological assessment and PSAA testing results can be used to support changes to the ICS site safety plan.[122] PSAA (presumptive) results cannot be used to definitively identify a hazard or be used to advise medical

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[120] Association of Public Health Laboratories, *Association of Public Health Laboratories Model*, 2.

[121] ASTM International. *E2770-10: Standard Guide for Operational Guidelines*.

[122] Occupational Safety and Health Administration, "Site Safety and Control Plan," Occupational Safety and Health Administration, retrieved July 12, 2013, from https://www.osha.gov/SLTC/etools/ics/pdf/ics208.pdf.

treatment protocols. That level of testing is defined as public health actionable assay (PHAA) and is accomplished by an LRN member, such as the state's public health laboratory.[123]

Certified training programs have not been developed on a national level. Some work has been done at the state level, which indicates that states are capable of developing and administering statewide training. In addition, 45 percent of the participating states indicated in the APHL survey that they had a bioresponse training program. As with the EMS example, states will need to take national guidance and develop their own training programs that are specific to their unique situations. Training programs should include the use of technology, risk assessment process, sample handling, documentation and evidence preservation. For a detailed training program explanation refer to ASTM E2770-10 Section 7.[124]

Georgia demonstrated a proficiency and competency evaluation exercise template during the Operation Vigilant Sample (OVS) exercise series. Two exercises were conducted in Georgia at the Federal Law Enforcement Training Center (FLETC)[125] and one was conducted at Fort Detrick's Biological Agent Identification and Counterterrorism Training (BAIT)[126] Center.[127] OVS was the first documented laboratory specific field exercise using gamma-irradiated *Bacillus anthracis* spores to verify proficiency at all levels of screening and testing. The exercises were conducted in real time from initial recognition of a suspicious substance to the final LRN determination of collected samples. On-site biological assessment and PSAA testing results were used to support the threat assessment hazard analysis process, and final LRN results were used to confirm risk determination.

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[123] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability*, 6.

[124] ASTM International. *E2770-10: Standard Guide for Operational Guidelines*, 6.

[125] Federal Law Enforcement Training Center. http://www.fletc.gov/ (accessed June 12, 2013)

[126] United States Army Medical Research Institute for Infectious Diseases, "Biological Agent Identification and Counter Terrorism Training," United States Army Medical Research Institute for Infectious Diseases, retrieved June 12, 2013, from http://www.usamriid.army.mil/education/docs/BAIT_2013.pdf.

[127] Morrow et al., "Building a National Biothreat Response Capability," 28

The exercises were conducted in collaboration with emergency responders, the 4th Civil Support Team, the FBI, and the state public health laboratory. The template is either a two-day exercise event that is flexible enough to tailor scenarios to meet the needs of any state. The OVS template provides a mechanism to meet the requirements of *ASTM E2770-10* Section 8. Attenuated select agents, such as the gamma-irradiated *B. anthracis* spores, can be used to conduct proficiency tests, or *S. cerevisiae* can be used to conduct confidence tests. The level of quality assurance needed can be determined by the state in conjunction with the LRN.

Sample collection and handling standards are defined in *ASTM E2458-10: Standard Practices for Bulk Sample Collection and Swab Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Surfaces*[128] and the CDC's *Surface Sampling Procedures for Bacillus Anthracis Spores from Smooth, Nonporous Surfaces*.[129] ASTM E2458-10 provides methods for bulk collection, while the CDC surface sampling procedures provide methods for trace collection. Other sample type methods such as liquid will need to be developed and validated. States can use their own sampling methods if validated methods are not available.

Efforts to develop biothreat detection performance standards have evolved over the past decade. The largest consensus effort to date involves the establishment of the stakeholder panel on agent assays (SPADA) by AOAC International, with funding from DHS Science and Technology Directorate (S&T).[130] SPADA, DHS S&T, and the *National Strategy for CBRNE Standards* ultimately set standards for detectors that can be purchased at the community level. Access to validated detectors with known performance standards will be an ongoing effort that demands federal oversight. Validated detection technology should support on-site biological assessment and PSAA testing. Every

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128 ASTM International, *E2458-10: Standard Practices for Bulk Sample Collection*.

129 Centers for Disease Control and Prevention, *Surface Sampling Procedures for Bacillus Anthracis Spores from Smooth, Nonporous Surfaces* (Atlanta, GA: Centers for Disease Control and Prevention, 2010), retrieved, May 1, 2012, from http://www.cdc.gov/niosh/topics/emres/surface-sampling-bacillus-anthracis.html.

130 Scott Coates, Sharon Brunelle, and Mattew Davenport, "Development of Standard Method Performance Requirements for Biological Threat Agent Detection Methods," *Journal of AOAC International* 94, no. 4 (2011): 1328–1337.

emergency responder organization that handles unknown material suspected of being a biothreat hazard will need basic on-site biological assessment technology, but not every organization will need PSAA detection. Communities that need PSAA detection are ones that have established high risk through a consequence, threat, and vulnerability assessment.

The cost of maintaining the equipment and the associated quality assurance program will make the technology prohibitive for the average community. PSAA detection platforms, such as PCR, can be regionally shared. The capability will not be needed often due to the low probability/high consequence nature of a biothreat event, but the capability should be available if needed. Regional capability can be structured similar to a state's explosive ordinance disposal (EOD) unit.

D. WHAT IS THE FRAMEWORK IMPLEMENTATION MODEL?

Implementation should occur in three phases in accordance with ASTM E2770-10 Sections 6, Plans, 7, Training, and 8, Competency Assessment Exercises.[131] Once implemented, the phases are cyclic and support the FEMA *Preparedness Cycle: Train, Exercise, Evaluate/Improve, and Organize/Equip*.[132] During implementation community, state, and federal responsibilities are assigned. Federally resourced agencies such as the CST, FBI, and CDC LRN will work with state and community level agencies throughout all three phases of implementation. The CST, FBI WMD coordinators and CDC LRN member laboratories are common to each state and are standardized. These agencies represent the core resources needed to implement a national framework at the community level. DHS will work with the CDC, FBI, and NGB to identify target states for implementation. States that voluntarily agree will need to identify participating agencies, locate training and exercise venues, and be willing to have their state plans and guidance documents reviewed at the end of the process in order to determine what elements of the framework were accepted or rejected.

[131] ASTM International. *E2770-10: Standard Guide for Operational Guidelines*, 5–6.

[132] Federal Emergency Management Agency, *National Preparedness Cycle*.

In phase I, training certification, state governments will incorporate federal guidance into their state specific training programs. Federally resourced agencies, CST, FBI, and the CDC LRN, will work at the state level to prepare the emergency responders identified for participation in phase II. The state agencies will be provided the basic information and outlines needed to conduct future training. This effort is best described as a "train-the-trainer," and it is intended to seed the community with the knowledge needed to create state specific training programs. The community and state agencies identified for implementation will receive training from the federally resourced agencies so that they are prepared to participate throughout the entire implementation process.

In addition, it is recommended that the FBI and CDC use the *Criminal and Epidemiological Investigation Handbook*,[133] ASTM E2770-10, and the APHL algorithm to assist states in developing their certified training programs. The FBI and CDC can facilitate the development of state curriculum that includes framework response ConOp, and the threat assessment and hazard analysis process. It is recommended that the CST, in collaboration with NIST and NIOSH, use the Coordinated FBI-DHS-HHS/CDC document, ASTM E2458-10, and the CDC surface sampling procedures to support training development. The CST can assist in training emergency responders on on-site biological assessment (i.e., screening) and sample collection. Local communities will be required to know and operate their specific detection technologies. At the end of phase I, participants should be able to:

- Conduct sample screening and hazard assessment in accordance with ASTM E2770 and coordinated FBI-DHS-HHS/CDC document
- Conduct sampling operations in accordance with *ASTM E2458-10* and the CDC surface sampling procedures when deemed appropriate
- Know the response ConOp in accordance with the *APHL Algorithm* and ASTM E2770-10

In phase II, competency and proficiency evaluation exercises, the CST will host a statewide full-scale bioresponse exercise in collaboration with the public health laboratory (LRN member) and the FBI WMD coordinator. Trained state and community

[133] Federal Bureau of Investigation and Centers for Disease Control and Prevention, *Criminal and Epidemiological Investigation Handbook: 2011 Edition*, Federal Bureau of Investigation and Centers for Disease Control and Prevention, 2011.

agencies from phase I will be required to respond in real time to a suspicious mailing and will conduct operations in accordance with their SOP and the framework ConOp. The state government in conjunction with the state public health laboratory will determine if they need to conduct proficiency (attenuated select agents) or confidence testing (yeast). The CDC LRN will supply proficiency challenge material; it is strongly recommended that an appropriate risk analysis be conducted to ensure proper controls are in place to reduce the possibility of unintentional contamination. Currently, confidence challenge material is supplied by NIST in limited quantity. It is recommended that DHS work the Critical Reagents Program (CRP)[134] to supply yeast assays for future implementation programs.

Furthermore, it is recommended that states undergoing phase II utilize the Georgia OVS exercise template. OVS is a two-day exercise. Day one is focused on responding to a suspicious mailing with bulk powder, and day two is designed to exercise a contamination response with trace sample collection. The scenario is designed to meet credible threat and emergency responders are required to collect bulk powder in accordance with ASTM E2458-10. After an on-site biological assessment, an FBI led hazard assessment and threat evaluation determines credible threat and the need to collect a sample. Sample collection is split samples at point of sample (methods A and B). Method A samples are sent to the state's public health laboratory for final determination; method B samples are tested by emergency responders if they have PSAA detection capability and by the CST mobile ALS laboratory. Day one ends when on-site results are known and the public health laboratory results can be incorporated during day two. Day two expands the response with a confirmed identification of a select agent. Sampling operations to determine the extent of contamination will be conducted using the CDC surface sampling procedures. On-site results can be used to update the hazard assessment and threat analysis process. At the end of phase II participants will be evaluated on:

[134] Joint Program Executive Office for Chemical and Biological Defense, "Critical Reagents Program," last modified July 17, 2013, Joint Program Executive Office for Chemical and Biological Defense, retrieved August, 12, 2013, http://www.jpeocbd.osd.mil/packs/Default.aspx?pg=1205.

- Competency in response ConOp, hazard assessment and threat analysis, and sample collection
- Confidence (if yeast is used) in on-site biological assessment and PSAA analysis
- Proficiency (if attenuated select agents are used) in PSAA and PHAA

In phase III, plans, an after action review (AAR) is conducted with all participating agencies in order to define what worked and what did not. AAR comments will be used to develop a "lessons learned" statement in order to identify best practices for updating state plans and guidance. Additionally, it is recommended that competency and proficiency results should be used to verify certification levels assigned during training. Upon conclusion of the AAR process, it is recommended that DHS review state plans to determine what was adopted and what was rejected. The three-phased implementation process should then be conducted again on an annual basis with other state emergency responders independently from federal support. Upon conclusion of Phase III participating agencies should be able to identify:

- Best practices
- Rejected practices
- Certified responders

E. FUTURE RESEARCH

It is recommended that additional research continue on the subject of implementation and community preparedness. While this research was extensive, it is by no means complete. Recommended areas for future research include, conducting a Delphi panel survey[135] of the states represented in the APHL survey. A Delphi panel is made of up experts from the bioresponse field, and the participating state BT coordinators demonstrated knowledge of the current state of implementation at the community level. A Delphi panel should seek to identify best practices and barriers to implementation in the areas of:

[135] The Delphi method is a structured communication process between participants who have expert insight into a field of study. Panel member responses are kept anonymous in order to facilitate open debate. The Delphi process is steered by an administrator who ensures exchanges stay focused and move towards consensus and agreement

- Certified training standards
- PSAA and Characterization technology
- Quality assurance program (to include logistics)
- Results integration into the ConOp

Additional research should also be conducted in measuring the impact of implementation to community preparedness. Metrics to measure preparedness indicators for each of the three phases have not been developed. Continual investment into the three phases of implementation (i.e., FEMA preparedness cycle, will require justification). Quantifiable differences in preparedness indicators, such as an increase in certified PSAA level technicians, will be provide compelling arguments for continued investment.

F. IMPLICATIONS AND RECOMMENDATIONS

It is recommended that a national quality assurance program be undertaken based on the lessons learned from the CST program. It is also recommended that the hosting agency start conversations with the NGB CST program in order to assess the feasibility of this concept. A quality assurance program is needed to ensure that PSAA results are reliable. It is observed in the APHL survey that states are acquiring next generation detection technology such as PCR platforms. The window for standardization will close if a quality assurance program is not implemented before this trend becomes established. If a national quality assurance program does not occur, states will most likely develop their own, resulting in signification variation. Variation in quality assurance will undermine the hazard assessment and threat evaluation process.

It is recommended that current and future detection technologies be reviewed to determine their suitability for supporting the hazard assessment process during characterization screening before sample collection. Characterization screening is a component of on-site biological assessment and should be used primarily for bulk sample incidents where the impact of sample consumption is minimal. It is recommended that characterization screening be completed during safety screening so that the results can be used to enhance the hazard assessment, determine sample collection points, and support any PSAA testing strategies. Because of the potential for false negatives, characterization

screening results should only be integrated into the ConOp in the absence of PSAA and PHAA results. Furthermore, screening results should only be used to elevate risk, not lower it. Jurisdictions choosing to integrate sample characterization into their on-scene biological assessment should ensure that personnel and test methods are supported by training and proficiency testing programs defined in ASTM E2770-10.[136]

It is recommended that a central logistics program take on the responsibility of supporting communities with a need for PSAA capability. Logistics can affect the quality of results and are a major component to any quality assurance program. Logistics must be standardized if results are required to be standardized. It is recommended that support be awarded to communities that have an established capability need as determined through a comprehensive risk analysis such as threat, vulnerability, and consequence (TVC).[137]

Finally, it is recommended that the three-phased implementation strategy be used as a template to quantitatively measure preparedness. Metrics that measure framework adoption in certified training and plans should be developed. Metrics could include the number of certified responders relative to communities' population, and the adoption level of national standards represented in state plans. Additionally, the competency and proficiency evaluation exercises are an opportunity to measure a community's actual response capabilities.

G. SUMMARY

Implementing a national biothreat response framework began with the publications of GAO-05-251, *Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results* and GAO-08-180, *First Responders' Ability to Detect and Model Hazardous Releases in Urban Areas is Significantly Limited.* NGB supported this process with the validation of a sample collection method ASTM E2458-

[136] ASTM International. *E2770-10: Standard Guide for Operational Guidelines*, 8.

[137] United States Government Accountability Office, *DHS Risk-Based Grant is Reasonable, But Current Version's Measure of Vulnerability is Limited* (GAO-08-852), (Washington, DC: United States Government Accountability Office, 2008), retrieved July 21, 2013, from http://www.gao.gov/assets/280/277552.pdf.

10.[138] The publication of a validated sample collection method accomplished the first critical element in the national framework.[139] The National Guard Civil Support Team program has supported the development of the framework from the start and should continue its support during implementation. Planning for fiscal year 2014 implementation exercises using the OVS template are underway. It is the intent of this research that the recommendation regarding the three-phased strategy be used to guide implementation activities.

[138] Locascio, "Department of Homeland Security and Committee E54;" Harper and Robinson, Method, Modification (2004.08).

[139] Department of Homeland Security, *Framework for Biothreat Field Response Mission Capability*, 4.

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APPENDIX. SURVEY SUMMARY

Linking Public Health Laboratories and First Responders

1. What state public health laboratory do you represent? This information will NOT be used to identify your laboratory in the data analysis. This will only be used to contact labs for the Delphi survey if they indicate an interest later in this survey.

	Response Count
	27
answered question	27
skipped question	0

2. Does your state have a bio-response training program for first responders (i.e. HAZMAT teams)?

	Response Percent	Response Count
Yes	45.0%	9
No	30.0%	6
Do not know	25.0%	5
Other (please specify)		5
answered question		20
skipped question		7

3. Is there collaboration in the development and delivery of the state's bio-response training between the public health laboratory and other organizations? Please check all that collaborate.

	Response Percent	Response Count
FBI WMD Coordinator	35.3%	6
National Guard Bureau Civil Support Team (CST)	**41.2%**	**7**
State Law Enforcement	0.0%	0
Local Law Enforcement	0.0%	0
Fire Department	0.0%	0
HAZMAT	17.6%	3
None	5.9%	1
	Other (please specify)	15
	answered question	**17**
	skipped question	**10**

4. At the successful completion of training are first responders assigned a certification level?

		Response Percent	Response Count
0 - No certification levels/No training available		35.0%	7
1 - Certification levels in progress, meetings and discussions have taken place		5.0%	1
2 - Single certification level assigned but not clearly defined as to what a first responder can and cannot do		0.0%	0
3 - Single certification level assigned and clearly defines what a first responder can and cannot do		5.0%	1
4 - Certification assigned as per level trained but not clearly defined as to what a first responder can and cannot do		0.0%	0
5 - Certification assigned as per level trained that clearly define what a first responder can and cannot do		5.0%	1
Do not know		**50.0%**	**10**
		answered question	**20**
		skipped question	**7**

5. Has your state incorporated the concept of presumptive analysis (PA) technologies into a biothreat response-training program? PA technology is the next level of field analysis after hazard assessment screening, i.e. RT-PCR.

	Response Percent	Response Count
Yes	25.0%	5
No	**75.0%**	**15**
If yes, please list the PA technology		3
	answered question	**20**
	skipped question	**7**

6. If your state incorporated the concept of PA technologies into a biothreat response-training program, please choose one of the options below:

	Response Percent	Response Count
0 - No PA training	**40.0%**	**2**
1 - PA training plans in progress, meetings and discussions have taken place	20.0%	1
2 - Initial PA training but not statewide, state may or may not expand program	0.0%	0
3 - Initial PA training but not statewide, state will expand program	0.0%	0
4 - Limited PA training program in place	20.0%	1
5 - Statewide PA training program	20.0%	1
	answered question	**5**
	skipped question	**22**

7. Does the state training curriculum include standardized risk assessment as per ASTM E2770-10 page 7 section 10?

	Response Percent	Response Count
0 - No standardized risk assessment training	30.0%	6
1 - Risk assessment mentioned in training but not explained	0.0%	0
2 - Risk assessment mentioned in training but not fully explained	0.0%	0
3 - Different version of risk assessment used in training	0.0%	0
4 - Risk assessment training similar to ASTM E2770-10	5.0%	1
5 - Risk assessment training as per ASTM E2770-10	20.0%	4
Do not know	**45.0%**	**9**
	answered question	**20**
	skipped question	**7**

8. Does the state training curriculum include standardized sample collection as per ASTM E2458-10 and/or the CDC's Surface Sampling Procedures?

	Response Percent	Response Count
0 - No standardized sample collection	20.0%	4
1 - Sample training mentioned in training but not explained	0.0%	0
2 - Sample training other than ASTM E2458-10 and the CDC's Surface Sampling Procedures	5.0%	1
3 - Sample training as per ASTM E2458-10 OR the CDC's Surface Sampling Procedures, but not hands on	0.0%	0
4 - Hands on sample training as per ASTM E2458-10 OR the CDC's Surface Sampling Procedures	15.0%	3
5 - Hands on sample training as per ASTM E2458-10 AND the CDC's Surface Sampling Procedures	15.0%	3
Do not know	**45.0%**	**9**
	answered question	**20**
	skipped question	**7**

9. What protocol does the state use for training first responders on how to screen samples? Please check all that apply.

		Response Percent	Response Count
State developed protocol		**58.8%**	**10**
FBI-DHS-HHS/CDC Coordinated document		17.6%	3
APHL Unknown Algorithm		11.8%	2
No training available to first responders		41.2%	7
		Other (please specify)	7
		answered question	**17**
		skipped question	**10**

10. Does the state training curriculum include standardized sample screening as per the FBI-DHS-HHS/CDC Coordinated Document? Field safety screening should be limited to ruling out explosive devices, radiological materials, corrosive materials and volatile organic compounds.

	Response Percent	Response Count
0 - No standardized sample screening	15.0%	3
1 - Sample screening mentioned in training but not explained	5.0%	1
2 - Sample screening other than the FBI-DHS-HHS/CDC Coordinated Document	5.0%	1
3 - Sample screening similar to the FBI-DHS-HHS/CDC Coordinated Document	0.0%	0
4 - Sample screening as per the FBI-DHS-HHS/CDC Coordinated Document but not hands on	15.0%	3
5 - Hands on sample screening as per the FBI-DHS-HHS/CDC Coordinated Document	15.0%	3
Do not know	**45.0%**	**9**
	answered question	**20**
	skipped question	**7**

11. Are there any activities regarding training that are not covered in this questionnaire that you would like to communicate?

	Response Count
	6
	answered question 6
	skipped question 21

12. Are competency assessments of biothreat response operations conducted in collaboration with the state public health laboratory? Please check all that apply. This question is not asking if your state laboratory is assessing responder competency but rather if they are participating in a competency assessment program with other agencies, i.e. do you receive samples from the field during an exercise? Competency assessment includes proficiency of emergency response personnel in knowledge, skills, and abilities identified in the training program. An assessment can be an exercise, test, or drill.

	Response Percent	Response Count
FBI WMD Coordinator	11.1%	2
National Guard Bureau Civil Support Team (CST)	**61.1%**	**11**
First Responder Community (i.e. HAZMAT teams)	27.8%	5
Law Enforcement	16.7%	3
None	38.9%	7
Other (please specify)		4
answered question		**18**
skipped question		**9**

13. Does your lab conduct functional exercises with your first responder community?

	Response Percent	Response Count
Yes	**55.0%**	**11**
No	45.0%	9
answered question		**20**
skipped question		**7**

14. Are functional exercises that are designed to evaluate first responder competency conducted in accordance with Homeland Security Exercise and Evaluation Program (HSEEP) when possible?

	Response Percent	Response Count
0 - No exercises conducted	9.1%	1
1 - Exercise meetings and discussions have taken place	9.1%	1
2 - Limited exercise, or table top exercise, conducted	0.0%	0
3 - Single exercise conducted in accordance with HSEEP	18.2%	2
4 - Ongoing exercise program not conducted in accordance with HSEEP	9.1%	1
5 - Ongoing exercise program conducted in accordance with HSEEP	**45.5%**	**5**
Do not know	9.1%	1
	answered question	**11**
	skipped question	**16**

15. Are field delivered proficiency panels (or unknown check samples) for first responders included in exercises? Field delivered proficiency panels (or unknown check samples) are used to characterize the capability of a first responder PA program to produce accurate results.

		Response Percent	Response Count
0 - No proficiency panels		**63.6%**	**7**
1 - Proficiency panels program in development		0.0%	0
2 - Proficiency panels demonstrated but not in field exercise		0.0%	0
3 - Proficiency panels demonstrated in field exercise		9.1%	1
4 - Ongoing proficiency panels program but not in field exercise		0.0%	0
5 - Ongoing proficiency panels program in field exercise		0.0%	0
Do not know		27.3%	3
		answered question	**11**
		skipped question	**16**

16. Do functional exercises evaluate first responder risk assessment as per ASTM E2770-10 page 7 Section 10?

		Response Percent	Response Count
0 - No evaluation of standardized risk assessment		18.2%	2
1 - Risk evaluation evaluated in table top exercise or some other format		18.2%	2
2 - Risk assessment occurs in an evaluated functional exercise but not specifically evaluated		9.1%	1
3 - Other risk evaluation method specifically evaluated in a functional exercise		9.1%	1
4 - Risk assessment as per ASTM E2770-10 evaluation demonstrated once during functional exercise		9.1%	1
5 - Ongoing risk assessment evaluation as per ASTM E2770-10 during a functional exercise program		9.1%	1
Do not know		**27.3%**	**3**
		answered question	**11**
		skipped question	**16**

17. Do functional exercises evaluate first responder sample collection as per ASTM E2458-10 and the CDC's Surface Sampling Procedures?

	Response Percent	Response Count
0 - No evaluation of standardized sample collection	**18.2%**	**2**
1 - Sample collection evaluated in table top exercise or some other format	**18.2%**	**2**
2 - Sample collection assessment occurs in an evaluated functional exercise but not specifically evaluated	9.1%	1
3 - Other sample collection method specifically evaluated in a functional exercise	9.1%	1
4 - Sample collection as per ASTM E2458-10 and the CDC's Surface Sampling Procedures demonstrated during functional exercise	**18.2%**	**2**
5 - Ongoing sample collection evaluation as per ASTM E2458-10 and the CDC's Surface Sampling Procedures during a functional exercise program	9.1%	1
Do not know	**18.2%**	**2**
	answered question	**11**
	skipped question	**16**

18. Do functional exercises evaluate first responder sample screening as per the FBI-DHS-HHS/CDC Coordinated Document?

	Response Percent	Response Count
0 - No evaluation of standardized sample screening	**27.3%**	**3**
1 - Sample screening evaluated in table top exercise or some other format	9.1%	1
2 - Sample screening assessment occurs in an evaluated functional exercise but not specifically evaluated	9.1%	1
3 - Other sample screening method specifically evaluated in a functional exercise	9.1%	1
4 - Sample screening as per the FBI-DHS-HHS/CDC Coordinated Document demonstrated during functional exercise	9.1%	1
5 - Ongoing Sample screening evaluation as per the FBI-DHS-HHS/CDC Coordinated Document during functional exercise	9.1%	1
Do not know	**27.3%**	**3**
	answered question	**11**
	skipped question	**16**

19. Are there any activities regarding competency assessment that are not covered in this questionnaire that you would like to communicate?

	Response Count
	3
answered question	3
skipped question	24

20. Is there collaboration between the public health laboratory and other agencies in the development of state bio-response plans or guidance for a first responder (i.e. HAZMAT teams) response to a suspicious substance event? If so, please check all that apply:

	Response Percent	Response Count
FBI WMD Coordinator	72.2%	13
National Guard Bureau Civil Support Team (CST)	66.7%	12
First responder community	66.7%	12
No state plans or guidance document	0.0%	0
No collaboration	11.1%	2
Other (please specify)		6
answered question		18
skipped question		9

21. Do state plans or guidance documents define roles and responsibilities for first responders?

		Response Percent	Response Count
0 - No roles or responsibilities defined		5.3%	1
1 - Defined roles and responsibilities in progress, meetings and discussions have taken place		15.8%	3
2 - Basic roles and responsibilities described, but work in progress		0.0%	0
3 - Roles and responsibilities mostly defined, some work needed		10.5%	2
4 - Roles and responsibilities defined in state plans and guidance demonstrated		**31.6%**	**6**
5 - Ongoing effort to define roles and responsibilities in state plans and guidance		5.3%	1
Do not know		**31.6%**	**6**
		answered question	**19**
		skipped question	**8**

22. Does your state have a plan or guidance on how to incorporate PA (not CST) results during a suspicious substance event?

	Response Percent	Response Count
0 - No PA included in plans or guidance documents	36.8%	7
1 - PA program in progress, meetings and discussions have taken place	5.3%	1
2 - Initial PA program described in plans and guidance, but state not ready for first responder use	0.0%	0
3 - Initial PA program described, some work still needed, i.e. no guidance on how to react to results	0.0%	0
4 - Defined PA program with guidance on how to react to results demonstrated	15.8%	3
5 - Ongoing effort to define PA program with guidance on how to react to results	0.0%	0
Do not know	**42.1%**	**8**
	answered question	**19**
	skipped question	**8**

23. Do state plans or guidance documents include standardized risk assessment per ASTM E2770-10 page 7 section 10?

		Response Percent	Response Count
0 - No standardized risk assessment included in state plans or guidance documents		0.0%	0
1 - Risk assessment plans and guidance in progress, meetings and discussions have taken place		15.8%	3
2 - Other risk assessment defined in plans and guidance		15.8%	3
3 - Standardized risk assessment as per ASTM E2770-10 reflected in state plans and guidance, but some work needed		0.0%	0
4 - Standardized risk assessment as per ASTM E2770-10 demonstrated in state plans and guidance		10.5%	2
5 - Ongoing effort to standardized risk assessment as per ASTM E2770-10 reflected in state plans and guidance		5.3%	1
Do not know		**52.6%**	**10**
		answered question	**19**
		skipped question	**8**

24. Do state plans or guidance documents include standardized sample collection as per ASTM E2458-10 and the CDC's Surface Sampling Procedures?

	Response Percent	Response Count
0 - No standardized sample collection included in state plans or guidance documents	11.1%	2
1 - Sample collection plans and guidance in progress, meetings and discussions have taken place	5.6%	1
2 - Other sample collection defined in plans and guidance	11.1%	2
3 - Standardized sample collection as per ASTM E2458-10 and/or CDC's Surface Sampling Procedures reflected in state plans and guidance, but some work needed	5.6%	1
4 - Standardized sample collection as per ASTM E2458-10 and the CDC's Surface Sampling Procedures demonstrated in state plans and guidance	5.6%	1
5 - Ongoing effort to standardized sample collection as per ASTM E2458-10 and the CDC's Surface Sampling Procedures reflected in state plans and guidance	16.7%	3
Do not know	**44.4%**	**8**
	answered question	**18**
	skipped question	**9**

25. Do state plans or guidance documents include standardized sample screening as per the FBI-DHS-HHS/CDC Coordinated Document?

	Response Percent	Response Count
0 - No standardized sample screening included in state plans	10.5%	2
1 - Sample screening plans and guidance in progress, meetings and discussions have taken place	5.3%	1
2 - Other sample screening defined in plans and guidance	10.5%	2
3 - Standardized sample screening as per the FBI-DHS-HHS/CDC Coordinated Document reflected in state plans and guidance, but some work needed	0.0%	0
4 - Standardized sample screening as per the FBI-DHS-HHS/CDC Coordinated Document demonstrated in state plans and guidance	21.1%	4
5 - Ongoing effort to standardize sample screening as per the FBI-DHS-HHS/CDC Coordinated Document reflected in state plans and guidance	10.5%	2
Do not know	**42.1%**	**8**
	answered question	**19**
	skipped question	**8**

26. Are there any activities regarding plans that are not covered in this questionnaire that you would like to communicate?

	Response Count
	2
answered question	2
skipped question	25

27. Would you be willing to participate in a follow up Delphi panel that aims to determine a consensus on best practices and barriers regarding implementation of training, competency assessments and plans? The Delphi method is a structured communication process between participants who have expert insight into a field of study. A series of survey rounds will be sent between the months of April and May. After each round answers will be calculated to provide statistical analysis and shared with the participants in order to move the discussion to additional exchange. Open question periods will last one week. Total rounds are estimated to be between two to four depending on the degree of variation communicated between the participants. The follow up survey rounds are not intended to be as in depth as the initial survey.

		Response Percent	Response Count
Yes		47.4%	9
No		52.6%	10
		answered question	19
		skipped question	8

Page 1, Q1. What state public health laboratory do you represent?

This information will NOT be used to identify your laboratory in the data analysis. This will only be used to contact labs for the Delphi survey if they indicate an interest later in this survey.

1	[redacted]	Apr 4, 2013 6:12 PM
2	[redacted]	Apr 4, 2013 2:22 PM
3	[redacted]	Apr 1, 2013 2:20 PM
4	[redacted]	Apr 1, 2013 11:14 AM
5	[redacted]	Apr 1, 2013 8:45 AM
6	[redacted]	Mar 29, 2013 5:26 PM
7	[redacted]	Mar 29, 2013 2:39 PM
8	[redacted]	Mar 28, 2013 1:51 PM
9	[redacted]	Mar 28, 2013 12:32 PM
10	[redacted]	Mar 27, 2013 5:46 PM
11	[redacted]	Mar 26, 2013 3:24 PM
12	[redacted]	Mar 26, 2013 11:21 AM
13	[redacted]	Mar 26, 2013 9:38 AM
14	[redacted]	Mar 26, 2013 9:33 AM
15	[redacted]	Mar 25, 2013 10:49 AM
16	[redacted]	Mar 25, 2013 10:28 AM
17	[redacted]	Mar 25, 2013 9:51 AM
18	[redacted]	Mar 25, 2013 8:43 AM
19	[redacted]	Mar 23, 2013 10:17 AM
20	[redacted]	Mar 22, 2013 4:03 PM
21	[redacted]	Mar 22, 2013 3:34 PM
22	[redacted]	Mar 22, 2013 3:13 PM
23	[redacted]	Mar 22, 2013 2:41 PM
24	[redacted]	Mar 22, 2013 2:39 PM
25	[redacted]	Mar 22, 2013 2:30 PM
26	[redacted]	Mar 22, 2013 2:25 PM

Page 1, Q1. What state public health laboratory do you represent? This information will NOT be used to identify your laboratory in the data analysis. This will only be used to contact labs for the Delphi survey if they indicate an interest later in this survey.		
27	[redacted]	Mar 22, 2013 2:24 PM

Page 2, Q2. Does your state have a bio-response training program for first responders (i.e. HAZMAT teams)?		
1	But we would like to start one	Apr 4, 2013 6:14 PM
2	Not yet, but we are working to design and implement a program	Apr 1, 2013 11:16 AM
3	I am in the process of establishing a training progam.	Apr 1, 2013 8:50 AM
4	CIty has HAZMAT teams as part of fire department	Mar 26, 2013 3:27 PM
5	We have initiated and developed a DVD that HAZMAT/Fire Responders can use as refresher.	Mar 22, 2013 2:38 PM

Page 2, Q3. Is there collaboration in the development and delivery of the state's bio-response training between the public health laboratory and other organizations? Please check all that collaborate.

1	We would engage all of the organizations in training	Apr 4, 2013 6:14 PM
2	FBI, CST, [redacted] Fire	Apr 4, 2013 2:24 PM
3	FBI WMD Coordinator	Apr 1, 2013 2:22 PM
4	plus FBI WMDCs & HAZMAT	Apr 1, 2013 11:16 AM
5	The survey would not allow me to choose more than one. I am working with the FBI, CST, state and local LE and the Fire Department.	Apr 1, 2013 8:50 AM
6	we have done exercises with our CST	Mar 26, 2013 9:34 AM
7	All, but unable to check all of them.	Mar 25, 2013 12:00 PM
8	All of the above.	Mar 25, 2013 10:34 AM
9	not working properly, wont allow multiple picks	Mar 25, 2013 8:46 AM
10	All of the above	Mar 23, 2013 10:19 AM
11	All of the Above - Wasn't able to check more than one box	Mar 22, 2013 4:27 PM
12	Not applicable	Mar 22, 2013 2:40 PM
13	[redacted]	Mar 22, 2013 2:38 PM
14	All of the above collaborate with [redacted], could not check more than 1 box.	Mar 22, 2013 2:28 PM
15	FBI reviewed the program	Mar 22, 2013 2:27 PM

Page 2, Q5. Has your state incorporated the concept of presumptive analysis (PA) technologies into a biothreat response-training program?

PA technology is the next level of field analysis after hazard assessment screening, i.e. RT-PCR.

1	LRN lab - the concept is that they need to provide the lab with sample to test by PA and for confirmatory testing	Mar 25, 2013 12:00 PM
2	[redacted] performs PCR, not certain of targets, CST trains most HazMat responders in [redacted]	Mar 22, 2013 2:28 PM
3	HHA currently, RT-PCR in progress	Mar 22, 2013 2:27 PM

Page 4, Q9. What protocol does the state use for training first responders on how to screen samples? Please check all that apply.		
1	But we would like to do this	Apr 4, 2013 6:15 PM
2	I have not established the specific training yet, but I will meet minimum FBI screening requirements.	Apr 1, 2013 8:53 AM
3	don't know	Mar 26, 2013 9:35 AM
4	Preparedness consortium training through [redacted] extension and [redacted] training program	Mar 25, 2013 12:02 PM
5	We introduced the APHL Unknown Algorithm SOP in a seminar held for First Responders on October 2012.	Mar 22, 2013 2:45 PM
6	We suggest screening be done according to FBI-DHS-HHS/CDC Coordinated document	Mar 22, 2013 2:42 PM
7	[redacted] has performed most HazMat Training for sampling in [redacted]	Mar 22, 2013 2:32 PM

Page 4, Q11. Are there any activities regarding training that are not covered in this questionnaire that you would like to communicate?		
1	We would really like to start a training program	Apr 4, 2013 6:15 PM
2	No	Mar 28, 2013 12:33 PM
3	Ensure that they have knowledge of interoperable communications and access to the state public health lab.	Mar 25, 2013 12:02 PM
4	We offer Peace Officer Standards and Training continuing education units with training	Mar 22, 2013 3:17 PM
5	The Biological Response Lab, the Chemical Response Lab and the [redacted] in [redacted] are working together to develop the training and a Proficiency Testing but still needs a total buy-in from the First responders. They liked the idea but we're hesitant to commit.	Mar 22, 2013 2:45 PM
6	Review of Incident Response Plan, Tour of Facilities for all HazMat FireFighters adn [redacted] for Tier I, Tour of Facilities for Medical Response for Firefighters, Secutiry Assessment with Local Law Enforcement	Mar 22, 2013 2:32 PM

Page 5, Q12. Are competency assessments of biothreat response operations conducted in collaboration with the state public health laboratory? Please check all that apply. This question is not asking if your state laboratory is assessing responder competency but rather if they are participating in a competen...		
1	I would like to implement these in the future.	Apr 1, 2013 8:57 AM
2	don't know	Mar 26, 2013 9:36 AM
3	Yes we receive samples from the First responders but a formal assessment of their competency is our goal this year.	Mar 22, 2013 2:48 PM
4	US Postal Inspection Service	Mar 22, 2013 2:43 PM

Page 7, Q19. Are there any activities regarding competency assessment that are not covered in this questionnaire that you would like to communicate?		
1	our CST performs proficiency panels, but the state lab is not involved	Mar 26, 2013 9:38 AM
2	CST are active for themselves, Army North evaluates them, we do not.	Mar 25, 2013 12:07 PM
3	Soem of these questions did not have appropriate choices- #16- We have functional exercises and perform sample collection as per E2458-10 only- not CDC surface sampling. Question #3- could only choose 1 but all should be selected for our response.	Mar 25, 2013 10:35 AM

Page 8, Q20. Is there collaboration between the public health laboratory and other agencies in the development of state bio-response plans or guidance for a first responder (i.e. HAZMAT teams) response to a suspicious substance event? If so, please check all that apply:		
1	In a sense the WMD Coordinators since we include as many of the FBI and LRN recommendations in our guide.	Apr 1, 2013 11:20 AM
2	This is in process, nothing has been formalized.	Apr 1, 2013 9:02 AM
3	Hazmat teams	Mar 25, 2013 12:12 PM
4	USPIS	Mar 22, 2013 4:29 PM
5	We work with the [redacted]	Mar 22, 2013 2:51 PM
6	HazMat, Postal Inspectors	Mar 22, 2013 2:34 PM

Page 8, Q26. Are there any activities regarding plans that are not covered in this questionnaire that you would like to communicate?		
1	The survey has assisted us in identifying a number of gaps in our program. We plan to meet with our Response Program staff to address these gaps.	Apr 1, 2013 2:31 PM
2	No	Mar 28, 2013 12:34 PM

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